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U.S. ARMY
MEDICAL RESEARCH
& DEVELOPMENT
COMMAND

ACQUISITION GUIDE

for

CONTRACTING OFFICER'S REPRESENTATIVES

and

PROGRAM OFFICERS

D 101.6/5:

READEX FICHE best copy available

FOREWORD

Technical personnel with a basic understanding of the acquisition process are essential to a cost-effective extramural research and development program. This Guide, in going beyond the obvious points of interest to the COR, provides an opening to that understanding. Accordingly, I strongly recommend that it become a well-read reference for all who plan, execute and oversee the USAMRDC extramural program.

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TABLE OF CONTENTS

SECTION I. INTRODUCTION 1

A. USAMRDC ACQUISITION OVERVIEW 1

- A.1 ACQUISITION ROLES 1
- A.2 ACQUISITION REGULATIONS 2
- A.3 ACQUISITION VS PROCUREMENT 3
- A.4 GRANTS 3

B. PERSONNEL ROLES IN THE ACQUISITION PROCESS 3

- B.1 PRE-AWARD PERIOD 3
- B.2 POST-AWARD PERIOD 4

C. THE ACQUISITION GUIDE 4

- C.1 PURPOSE 4
- C.2 INTENDED AUDIENCE 5

SECTION II. ACQUISITION BASICS 7

A. CONTRACTING BASICS 7

- A.1 NATURE OF A CONTRACT 8
- A.2 AUTHORITY TO ENTER INTO CONTRACTS 9

B. METHODS OF ACQUISITION 10

- B.1 COMPETITION IN CONTRACTING 10
- B.2 SPECIAL SOCIOECONOMIC ACQUISITION PROGRAMS 12
- B.3 CONTRACTING BY NEGOTIATION 13
- B.4 UNSOLICITED PROPOSALS 15
- B.5 GRANTS 16
- B.6 SMALL PURCHASES 16

C. TYPES OF CONTRACTS 18

- C.1 FIXED-PRICE CONTRACTS 18
- C.2 COST-REIMBURSEMENT CONTRACTS 19
- C.3 GRANTS 21

D. METHODS OF FUNDING 21

- D.1 FULL FUNDING 21
- D.2 INCREMENTAL FUNDING 21
- D.3 OPTIONS 22

SECTION III. ADVANCE ACQUISITION PLANNING 23

A. ADVANCE PLANNING AND SCHEDULING 23

  A.1 CONCEPT DEVELOPMENT 24
  A.2 MATERIEL ACQUISITION PROCESS 24
  A.3 RESPONSIBILITIES FOR ACQUISITION PLANNING 24

B. ADVANCE PLANNING ISSUES 25

  B.1 BACKGROUND OF THE ACQUISITION 25
  B.2 OBJECTIVES OF THE ACQUISITION 26
  B.3 PLAN OF ACTION 27

C. SPECIAL APPROVALS AND CLEARANCES 29

D. RESEARCH ACQUISITION PATHS 32

  D.1 ACQUISITIONS PLANNING 32
  D.2 BROAD AGENCY ANNOUNCEMENT (BAA) 33
  D.3 INTRAGOVERNMENTAL TRANSFER OF FUNDS 33
  D.4 GRANTS 33

E. THE STATEMENT OF WORK (SOW).............................. 34

  E.1 COMMON ELEMENTS OF SOW 35
  E.2 STEPS IN WRITING A SOW 38

F. INDEPENDENT GOVERNMENT COST ESTIMATES 44

  F.1 GENERAL INFORMATION 44
  F.2 STEPS IN DEVELOPING INDEPENDENT COST ESTIMATES 45

G. TECHNICAL EVALUATION PLANNING 46

  G.1 PLANNING FOR TECHNICAL EVALUATION OF PROPOSALS 46
  G.2 PURPOSE OF TECHNICAL EVALUATION CRITERIA 46
  G.3 SELECTING AND DEVELOPING EVALUATION CRITERIA 47
  G.4 WEIGHTING CRITERIA 48
  G.5 COST AS A CRITERION 49
  G.6 SAMPLE EVALUATION CRITERIA FORMAT 49
  G.7 EVALUATION WORKSHEET 50

H. SOLICITATION SCHEDULE 51

I. CONTRACTING FOR DEVELOPMENT 52

SECTION IV. SOLICITATION AND AWARD **53**

A. THE REQUEST FOR PROPOSAL (RFP) 53

A.1 UNIFORM CONTRACT FORMAT 54
A.2 PRE-PROPOSAL CONFERENCES 55
A.3 AMENDING THE SOLICITATION 56

B. SOLICITATION PERIOD 56

B.1 RECEIPT AND MANAGEMENT OF PROPOSALS 56
B.2 COMMUNICATION WITH OFFERORS 57

C. REVIEW OF PROPOSALS 58

C.1 SOURCE SELECTION EVALUATION BOARD 58
C.2 ROLE OF THE PROGRAM OFFICER 59
C.3 READING AND SCORING PROPOSALS 59
C.4 THE SOURCE SELECTION EVALUATION BOARD REPORT 61
C.5 REVIEW OF BUSINESS/COST PROPOSALS 61
C.6 DETERMINING THE COMPETITIVE RANGE 62

D. NEGOTIATIONS 64

D.1 WRITTEN AND ORAL DISCUSSION 64
D.2 BEST AND FINAL OFFERS 65
D.3 THE BUSINESS CLEARANCE MEMORANDUM 65

E. SELECTION AND AWARD 66

F. POST AWARD ACTIVITIES 66

F.1 PUBLICIZING THE AWARD 66
F.2 DEBRIEFING UNSUCCESSFUL OFFERORS 67
F.3 PROTESTS 67

SECTION V. CONTRACTING OFFICER'S REPRESENTATIVE (COR) ... **69**

A. COR APPOINTMENT 69

B. COR RESPONSIBILITIES 69

C. COR CONTRACT FILES 71

D. COR CAUTIONS 71

E. COR COMMUNICATIONS 72

F. MISCONDUCT IN SCIENCE 73

SECTION VI. POST-AWARD ADMINISTRATION 75

A. CONTRACT ADMINISTRATION 75

A.1 LIMITATIONS ON THE COR 76
A.2 PLANNING FOR ADMINISTRATION 77
A.3 CONTRACT REVIEW 78
A.4 POST-AWARD ORIENTATION AND CONFERENCES 80
A.5 PRIOR AUTHORIZATION FOR EXPENDITURES 81
A.6 COST AND SCHEDULE PERFORMANCE DATA 88
A.7 GOVERNMENT PROPERTY 82
A.8 KEY PERSONNEL CLAUSE 83

B. SUBCONTRACTS... 83

B.1 ADMINISTRATION OF SUBCONTRACTS 84
B.2 ACTION PRIOR TO AWARD 84
B.3 ACTION AFTER SUBCONTRACT AWARD 85

C. CONTRACT MONITORING 86

C.1 THE NEED TO MONITOR 87
C.2 PROGRESS REPORTS 87
C.3 SITE VISITS 90

D. CONTRACT MODIFICATIONS 91

D.1 CONSIDERATION FOR CONTRACT MODIFICATION 92
D.2 MODIFICATION VERSUS NEW ACQUISITION 92
D.3 CHANGE ORDERS 93
D.4 CONSTRUCTIVE CHANGES 93
D.5 SOME COMMON USAMRDC CONTRACT ACTIONS 96

E. CONTRACT PERFORMANCE PROBLEMS 98

E.1 COST OVERRUNS 98
E.2 INADEQUATE CONTRACTOR PERFORMANCE 100
E.3 WITHHOLDING PAYMENT 100
E.4 TERMINATIONS 101
E.5 PROCEDURES FOR DISCONTINUANCE OF USAMRDC SUPPORT . 102
E.6 RESOLVING DISPUTES 103

F. AT THE END OF THE CONTRACT 104

F.1 INSPECTION AND ACCEPTANCE RESPONSIBILITIES 104
F.2 CONTRACT REVIEW AND ANALYSIS 104
F.3 CONTRACT CLOSEOUT 105
F.4 CONTRACT AND PROJECT FILES 107

SECTION VII. STANDARDS OF CONDUCT **109**

- A. GRATUITIES 109
- B. CONFLICT OF INTEREST 109
- C. USE OF OFFICIAL INFORMATION 110
- D. PROTECTING THE INTEGRITY OF THE ACQUISITION PROCESS 111
- E. FRAUD IN GOVERNMENT CONTRACTS 111

APPENDICES **113**

- A. FORMAT TO JUSTIFY OTHER THAN FULL/OPEN COMPETITION. 113
- B. USE OF HUMANS AS SUBJECTS IN EXTRAMURAL RESEARCH .. 117
- C. RESEARCH INVOLVING ANIMALS 131
- D. TECHNICAL CRITERIA EVALUATION WORKSHEET 133
- E. SIMPLIFIED MEDICAL MATERIEL ACQUISITION PROCESS ... 135
- F. BROAD AGENCY ANNOUNCEMENT (BAA) PROCEDURES 137
- G. SOLICITATION OUTLINE 145
- H. CONTRACTING FOR DEVELOPMENT 147
- I. PROCEDURES FOR AVOIDING CONFLICT OF INTEREST 161
- J. SITE VISIT CHECKLIST 163
- K. PROGRESS / PERFORMANCE REPORT REQUIREMENTS 165
- L. USAMRDC FORM 9 181
- M. INTRAGOVERNMENTAL TRANSFER OF FUNDS 183
- N. WRITING STATEMENTS OF WORK 185

GLOSSARY **197**

INDEX **203**

SECTION I: INTRODUCTION

A. USAMRDC ACQUISITION OVERVIEW

Each year, the US Army Medical Research and Development Command (USAMRDC) invests millions of dollars in the research and development extramural program. Those investments, in turn, require further commitment in USAMRDC manpower and dollars because each contract, grant, and intragovernment order must be planned and monitored by both contracting and technical program personnel whose duty is to ensure that the Government receives fair value for its money and acts in a correct and legal manner. (Except where specifically indicated, the contract process described also applied generally to grants and intragovernmental orders.)

A.1 ACQUISITION ROLES

There are a great number of personnel performing myriad tasks on behalf of the USAMRDC extramural research and development acquisition process. Using broad definitions in some cases, it is possible to place a practical limit on the number of identifiable roles. As used in this Guide, those roles are:

Head of Contracting Activity (HCA) -- The Commanding General, USAMRDC, who is ultimately responsible for the effective and legal execution of the entire USAMRDC acquisition program.

Principal Assistant Responsible for Contracting (PARC) -- The alter ego of the Head of Contracting Activity for all delegated acquisition functions. The senior staff official responsible for oversight and administration of the contracting function within USAMRDC, the PARC promulgates policy and direction both for contracting and for acquisition from intragovernmental sources.

Contracting Officer or Grant Officer -- The individual warranted as the Government's authorized agent in dealing with contractors and would-be contractors. The CO or GO, alone, has the authority to negotiate and award contracts and grants on behalf of the Government, and to make changes and amendments. In this Guide, references to Contracting Officer or Grant Officer include contract specialists and other staff of the U.S. Army Medical Research Acquisition Activity (USAMRAA), as appropriate to the action.

Program Officer (PO) -- A generic reference to the technical and technical management personnel who have or are assigned the responsibility of overseeing or aiding with the acquisition of mission-important extramural research or development projects through contracts or intragovernmental sources. In general, PO are the people who identify scientific needs and/or provide the technical planning and guidance for the acquisitions. After the award, the PO might continue his involvement with a particular contract or project as someone interested in its outcome for program planning purposes, or as the Contracting Officer's Representative (see below).

Contracting Officer's Representative (COR) or Grant Officer's Representative (GOR) -- The technical, or program person who is appointed by the Contracting Officer or Grant Officer to monitor the technical, or scientific aspects of a contract or grant effort on behalf of the Government. While the contract or grant is in force, CORs/GORs will insure contractor/grantee compliance with all contract/grant provisions and applicable laws, and shall report any deviations to the Contracting Officer/Grant Officer.

Acquisition Management Liaison Office (AMLO) -- An acquisition staff function found in all USAMRDC laboratories and institutes having significant extramural research interests or commitments. The precise role of each AMLO in the acquisitions process depends on the desires of the local commander. Typically, AMLO serve as their commander's liaison with the acquisition process, coordinate and facilitate the acquisitions responsibilities of the laboratory/institute, and provide assistance that will increase the effectiveness and ease the burden of the COR tasks in their laboratory/institute. Each AMLO will normally describe local policy in written directives and in briefings.

Contractor or Grantee -- An organization which enters into a written agreement (contract) with USAMRDC (Government) to provide stated services (research, etc) for certain costs. Note that the contractor is an organization (corporation, university, etc), not an individual.

Principal Investigator (PI) -- The individual(s) with the primary role in conducting or coordinating the contract effort for the contractor. This is the person with whom the COR is most likely to have direct contact during the performance of the contract. It is important that the PI realizes that he cannot obligate his organization to any contractual change.

A.2 ACQUISITION REGULATIONS

The USAMRDC acquisition process is governed by three separate, but related regulations: The Federal Acquisition Regulation (FAR), the DOD Supplement (DFARS), and the US Army supplement (AFARS). References to these documents appear in this manual.

Copies of the documents can be found in the USAMRDC Acquisition Management Office and may be accessed through the US Army Medical Research Acquisition Activity (USAMRAA) automated Computer-Aided Procurement System (CAPS).

The FAR is the primary regulation for use by all Federal agencies when they acquire supplies and services with appropriated funds. It was developed in accordance with the requirements of the Office of Federal Procurement Policy Act of 1974, as amended by Public Law 96-83. The FAR provides for coordination, simplicity, and uniformity in the Federal acquisition process. It is written in clear, straightforward language and is easy to use and understand.

DFARS and AFARS implement and supplement the FAR. They establish uniform acquisition policies and procedures for the DOD and Army that conform to the FAR System. They contain all formal policies and procedures governing the acquisition process or otherwise controlling relationships between the Contracting Officer and contractors.

Provisions of FAR, DFARS and AFARS are, in turn, implemented and supplemented by USAMRDC Acquisition Instructions. The latter are promulgated by the Principal Assistant Responsible for Contracting (PARC) on behalf of the Head of Contracting Activity (HCA). The Acquisition Instructions are, in effect, the working procedures for conducting the USAMRDC acquisition process. A copy of the USAMRDC Acquisition Instructions is available in every AMLO.

A.3 ACQUISITION

The term "acquisition" means the process for obtaining systems, equipment or modifications to existing inventory items. The procurement function is a part of the acquisition process; this Acquisition Guide covers the procurement process. The Medical Materiel Acquisition Management Handbook, available from the U.S. Army Medical Materiel Development Activity describes all aspects of medical materiel acquisition, including Life Cycle System Management.

A.4 GRANTS

Grants are made by DoD pursuant to 10 U.S.C. 2358. The acquisition regulations cited in A.3 above do not apply to grants. A compendium of federal statutes and regulations for use of grant officers will be issued by DoD in the near future.

B. PERSONNEL ROLES IN THE ACQUISITION PROCESS

B.1 PRE-AWARD PERIOD

Once a decision is made to acquire products or services through the contracting process, a partnership is created between PO and CO. This partnership is essential to establishing and achieving contract objectives because these two officials are responsible for ensuring that the contracting process is successful. CO and PO have both separate and mutual responsibilities. The lead responsibility shifts from one to the other during the various stages of the contracting process.

During the advance procurement planning phase, the PO has the lead, and the CO operates in an advisory capacity. As representatives of the technical or scientific program, PO must ensure that program requirements are clearly defined and that the contract is designed to meet them. They are responsible for advising that proposals are properly evaluated and that the price the Government pays for the services it acquires is reasonable. They must establish quality standards and delivery requirements. As the solicitation and award phase begins, the lead responsibility shifts to the CO, with the PO acting largely as an advisor. CO sign on behalf of the Government and bear the legal responsibility for the contract. They alone can enter into, terminate, or change a contractual commitment on behalf of the Government.

B.2 POST-AWARD PERIOD

During the post-award period, the COR assumes the lead responsibility for monitoring contractor, or PI performance for compliance with all contract provisions and applicable laws. He becomes the advisor to the Contracting Officer, who retains the legal responsibility for all contract actions, and to the Program Officer who has planning interests in the contract effort and its results. In some cases, the COR and the Program Officer may be one and the same person. Thorough, timely communications between COR and Contracting Officer, and between COR and Program Officer are essential to effective, legal execution of the extramural research and development program.

C. THE ACQUISITION GUIDE

C.1 PURPOSE

The responsibilities and specific duties of the contracts people on the extramural research program team are detailed in the Federal, Department of Defense (DOD) and Army Acquisition Regulations. The analogous responsibilities and duties for program management people are found in the same regulations; unfortunately, they are scattered under many different headings and are, therefore, difficult to locate. This Guide consolidates that material, combines it with USAMRDC policy, and presents it in a fashion which more or less traces a path from acquisition fundamentals, through planning and solicitation, to post-award administration.

The Guide does not have the force of regulation, although it is based on the regulations. It is intended to guide Contracting Officer Representatives (COR) and other technical program personnel through the procurement process; to outline and explain many of the factors affecting and the major steps in the Federal procurement process; to delineate the duties of the COR; and to bring into focus the separate and mutual responsibilities and relationships between the COR and the Contracting Officer. The information is applicable to all USAMRDC COR.

C.2 INTENDED AUDIENCE

This Guide has been written for program people; particularly, those who bear the title of Contracting Officer's Representative. It is a collection and distillation of laws, regulations, and policies relating to their role in the USAMRDC acquisition process. There will be too much material for some users, and too little material for others. But, all in all, the Guide is a reasonable and accurate first-source of information for both the serious and casual readers.

Contracting Officer's Representatives (COR) who must get to the immediate essentials of their appointed role are directed to Sections I, V, VI and VII. A later reading or perusal of Sections II, III and IV will greatly enhance the overall value of the COR to the extramural research and development program.

SECTION II. ACQUISITION BASICS

This section of the Guide describes the fundamentals of contract law and key principles of the procurement process. Familiarity with these basic concepts and terms can help PO and COR fulfill their responsibilities and know when to seek assistance from CO as problems arise.

Procurement, for purposes of this guide, encompasses the processes USAMRDC employs to obtain goods or services from outside the Command. It may be regarded as having two prongs -- Acquisition and Intragovernmental Transfer of Funds.

In general, the term Acquisition is used when the proposed purpose of the funding instrument to be executed is "the acquisition by purchase, lease, or barter of goods or services for the direct benefit or use of the Federal Government." Contracts, grants and purchase orders are the common instruments used in the acquisition process. The greater part of this section deals with Acquisition, particularly as it applies to contracts.

The Intragovernmental Transfer of Funds helps to support other Governmental agencies (Air Force, Navy, DOE, etc.) who conduct studies on behalf of USAMRDC mission needs. Such efforts are usually the result of direct interagency agreements or proposals from other agencies which USAMRDC regards as sound R and D investments. It is important to realize that transfer agreements may be written to include reporting and procedural requirements found in most USAMRDC contracts.

A. CONTRACTING BASICS

Contracts are used when USAMRDC must acquire research, development products, and such services as:

- Evaluation (including research of an evaluative nature) of the performance of programs or projects.
- Technical assistance.
- Consulting services or professional services of all kinds.
- Conferences.

A.1 NATURE OF A CONTRACT

A contract can be defined as an agreement between two or more parties consisting of a promise, or mutual promises, for breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty. Unlike most social exchanges of promises, a contract establishes a binding legal relationship that obligates parties to keep their promises. In nearly all Government contracts, one party is a "seller" obligated by the contract to provide goods or services. The other party is the Government which, as the "buyer," is obligated to pay for those goods or services.

All contracts contain three elements:

- **The offer**-- A proposal by a competent offeror that a contract be entered into;
- **The acceptance**-- The expression by the offeree of his/her assent to the offer and communication of that assent to the offeror; and
- **Consideration**-- Something of value in the eyes of the law exchanged by the parties to bind the agreement.

In Government contracting, the proposal is the offer. It is made by an offeror seeking to enter into a contract with the Government. A Request for Proposal (RFP) is not an offer. Rather it is an informational document that express the Government's needs to the community of potential offerors.

When the Government, after proposal review and negotiation, chooses an offeror to contract with, it performs the act of acceptance. The consideration in Government contracts is usually payment by the Government and delivery of supplies or services by the contractor.

There are other requirements for the formation of contracts. A contract must have a lawful purpose. It cannot violate a statute, for example. Contracts must be entered into by competent parties, who must be mentally and legally competent for the contract to be valid.

Contracts must have certainty of terms and conditions to be enforceable. Since courts have to rely on the meaning of the language of a contract to enforce it, this language must be clear and certain. Specifications or statements of work, for example, must communicate clear requirements. Although non-Government contracts may sometimes be oral, Government contracts (including modifications) are always in writing.

A.2 AUTHORITY TO ENTER INTO CONTRACTS

Although the United States is a legal entity having authority to enter into contracts and administer them, it is a legal abstraction. It must act by and through "agents" or human representatives. An agent is a person who has been authorized by another (called the "principal") to act for him/ her. An agent's acts are binding on the principal to the extent that these acts are within the authority given to the agent.

All persons involved in making or administering U.S. Government contracts act solely as agents of the United States and have only the authority delegated to them.

In USAMRDC, as in other Federal departments and agencies, the authority to contract is delegated to certain key officials who, in turn, redelegate this authority to CO. Although CO, in turn, may redelegate certain limited authority to administer parts of the contract, they are the only persons (with a few limited exceptions) authorized to enter into or modify contracts on behalf of the Government and USAMRDC.

CO have an important stewardship role in the acquisition process. They act as the United States' agents for the acquisition of goods and services. They are responsible to ensure that contractors live up to their contracted obligations. PO must ensure that they do nothing to infringe upon unique CO responsibilities. PO may be given certain limited authority to act on behalf of CO--particularly in providing technical direction to the contractor. This authority will be discussed in Section VI of this Guide, Post-Award Administration. It is important to point out that PO cannot obligate the Government or change the terms or conditions of contracts. Only the CO can do that.

Just as the Government requires agents to act on its behalf, so does the other party to the contract--the contractor. Agents will almost always be used by the contractor--necessarily so if the contractor is a corporation--to enter into and carry out the contract with the Government. One important difference is that only a person with actual authority (by statute, regulation, or contract terms) may bind the Government. An agent with apparent as well as actual authority may bind the contractor. However, even contractors usually try to limit and specify those who are their agents authorized to act on their behalf.

B. METHODS OF ACQUISITION

Federal law defines acquisition methods and processes. Although these methods and processes differ substantially, they have in common the goal of enhancing competition in contracting. Full and open competition in Federal contracting is the norm. Deviations from the norm are possible but require careful justification and high-level approval.

Maximum competition is desirable from a public policy perspective. It is also desirable because, if properly administered, competition in contracting will result in the timely delivery to the Government of quality products and services at a reasonable cost.

Acquisition can be looked at in two dimensions. One dimension describes the acquisition methods in terms of degree of competition. The other dimension describes the different process activities involved in implementing a particular method.

B.1 COMPETITION IN CONTRACTING

Full and Open Competition is the most desirable and favored form of contracting. This category includes contracting through:

- Sealed bids;
- Competitive proposals; and
- Other procedures.

Sealed bidding is used when requirements and solicitations are clear and unambiguous. Contractors can prepare and submit bids, and the Government can award strictly on price and on factors related to price. After submission of bids no discussion between the Government and bidders is permitted. This form of contracting is seldom used for USAMRDC R&D purposes.

Competitive proposals are offers made in response to solicitations that have the possibility of being interpreted with varying degrees of difference by offerors. Often, some discussion is required between the Government and offerors, resulting in modifications to those offers or proposals.

Whether sealed bids or competitive proposals are selected, under full and open competition there is potentially a large pool of prospective bidders or offerors. The more bids or proposals, the better the chances for the Government to obtain a good "buy."

The next degree of competition is obtained when the Government provides for Full and Open Competition After Exclusion of Sources. This procedure, somewhat less competitive than full and open competition, is used when the Government excludes certain potential bidders or offerors from consideration for a contract in order to establish or maintain alternative sources. This procedure is used to reduce the Government's dependency on one or a few sources or to increase the manufacturing or supply base for national defense reasons.

Exclusion of sources is also used for set-aside of acquisitions for small businesses, small and disadvantaged businesses, and labor surplus concerns.

Other Than Full and Open Competition is the least competitive method of acquiring goods and services. Under the method, a bid or proposal is solicited from only one or a few sources. This kind of contracting can be done only in limited circumstances. Some example conditions are:

- Only one responsible source exists (a sole source acquisition).
- The agency's need is of such an unusual and compelling urgency that the Government would be seriously injured unless the agency is permitted to limit the number of sources solicited.
- It is necessary to award the contract to a particular source or sources to maintain a mobilization capacity in a national emergency; or to set up and maintain a source of essential engineering, developmental, or research work.
- An international agreement precludes full and open competition.
- A Federal statute authorizes or requires acquisition through certain sources (e.g., Federal Prison Industries, certain agencies for the blind, utility services, and Government printing and binding).
- Disclosure of the agency's needs would compromise the national security unless the number of solicited sources is limited.
- An agency head determines that it is not in the public interest to have full and open competition.

Detailed justifications are required for choosing other than full and open competition as a means of contracting. These must offer reasons which go beyond inconvenience, and which are supported by verifiable facts rather than mere opinions. High-level approvals are also required. Appendix A : "Format for Justification and Approval for Other Than Full and Open Competition", portrays the extra effort required for this method of acquisition.

Prospective requests for acquisition through other than full and open competition should be discussed with the CO as early as possible in the planning stage. This is an acquisition path of many problems and uncertainties.

B.2 SPECIAL SOCIOECONOMIC ACQUISITION PROGRAMS

An important Governmental policy is to place a fair proportion of its acquisitions with small business concerns, small and disadvantaged business concerns, and business concerns located in labor surplus areas. It is Government policy to ensure that such concerns also shall have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance.

Within USAMRDC, the functional management responsibilities for small business, disadvantaged business, and labor surplus area programs are delegated to the Associate Director of Small and Disadvantaged Business Utilization (ADSADBU) in the USAMRDC Acquisition Management Office. The ADSADBU has the responsibility to locate capable small business, disadvantaged businesses, and labor surplus area business sources for current and future acquisitions. It also must ensure that contracting and technical staff are knowledgeable about these program requirements and that they take all reasonable action to increase small business participation in their contracting processes.

The ADSADBU must review each proposed acquisition prior to the CO review to determine the feasibility of recommending award to Small Business Administration (SBA) pursuant to section 8(a) of the Small Business Act. When a contract is not appropriate for an 8(a) award, the ADSADBU must then review the proposed acquisition to determine if it can be recommended as a total or partial set-aside for small business concerns or as a labor surplus set-aside of any kind.

Although the primary responsibility for implementing these policies rests with the contracting office, PO should be knowledgeable about these programs and should take steps to include these businesses in their acquisitions. They are listed and defined on the next page.

- Small Business Concerns. A concern, including its affiliates, that is independently owned and operated, not dominant in the field operation in which it is bidding on Government contracts, and qualified as a small business under the criteria established by the SBA (For R&D purposes, a small business is defined as one with 500 or fewer employees.)

- Small Disadvantaged Business Concerns. A small business concern that (a) is at least 51 percent owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business having at least 51 percent of its stock owned by one or more such individuals, and (b) has its management and daily business controlled by one or more such individuals.

- Labor Surplus Area Concerns. A concern that, together with its first-tier subcontractors, will perform substantially in labor surplus areas, geographical areas defined by the Department of Labor as an area of concentrated unemployment, underemployment or of labor surplus. Performance is substantially in labor surplus areas if the costs incurred under the contract in labor surplus areas exceed 50 percent of the contract price.

B.3 CONTRACTING BY NEGOTIATION

Many acquisitions in which COR and PO will be involved are made through the process of contracting by negotiation. Because of the nature of the USAMRDC mission contract requirements, it is not often possible to develop a set of totally unambiguous specifications such as are required for sealed bids. In addition, given the nature of these requirements, award may have to be made on the basis of factors in addition to price or cost. These factors often relate to the proposed technical approach, and quality of the staff.

In addition, the requirements and the specifications for such acquisitions frequently result in offers that must be clarified through discussion after they are submitted.

Request For Proposal (RFP)

Contracting by negotiation includes several discrete steps. After the requirement is determined and the acquisition is planned according to USAMRDC requirements, an advance notice or synopsis must be published in the Commerce Business Daily to inform the contracting community of the forthcoming solicitation.

A Request for Proposal (RFP) is prepared and transmitted to a number of sources, many of whom comprise an established list of offerors and many of whom responded to the Commerce Business Daily synopsis. Offerors then prepare and submit proposals in response to the RFP. These proposals consist of a technical proposal and a business or cost proposal.

The technical proposals are evaluated by a Source Selection Evaluation Board (SSEB) against a set of technical evaluation criteria that were included in the RFP. The cost proposals also are evaluated to determine whether the proposed costs and prices are reasonable, and to determine the offerors' understanding of the work and their ability to perform the contract.

The CO next determines which proposals are in the competitive range for the purpose of conducting written or oral discussions. The determination is made on the basis of cost and technical factors. Proposals are included in the competitive range when they have a reasonable chance of being selected for award.

The next step is the conduct of oral or written discussions. Although this is not a mandatory step, it is usually done. During these discussions, the Government attempts to resolve uncertainties concerning the technical proposal and to provide the offerors with reasonable opportunity to submit cost or technical revisions to their proposal as a result of the discussion.

After discussions are concluded, the CO issues a request for "best and final" offers from all offerors in the competitive range. Usually, no further discussions are held, although the Government has the right to reopen discussions and to request additional best and final offers.

The next step is evaluation of best and final offers and selection of the source to perform the contract. Selection is made of that source whose best and final offer is most advantageous to the Government considering cost and the other factors included in the solicitation.

Any type of contract may be used in the contracting by negotiation process. The foregoing steps constitute the negotiation process. This Guide will discuss each step in more detail in later sections.

Broad Agency Announcement (BAA)

The Competition in Contracting Act (CICA) issued as PL 98-369 authorizes the use of a Broad Agency Announcement (BAA) as a general solicitation for basic research proposals. The Act also requires evaluation of those proposals through peer or scientific review rather than by formal Source Selection Evaluation Boards. Contracts awarded under the BAA meet the "Full and Open" competition requirements of CICA.

The BAA process recognizes that the selection of a basic research contractor is primarily a technical decision, with very low business risk. Its purposes are to accelerate the acquisition process and to save on the significant costs and efforts associated with that process.

Reference to "basic research" has been interpreted to include research efforts funded from the 6.1, 6.2 and 6.3a budget categories. To be applicable to the BAA program, the desired research effort should be an attempt to increase knowledge and/or advance the state of the art in science. This is distinguished from efforts whose primary aim is the design, development, or test of specific items or services. The reference also does not apply to the purchase of technical or general support services, hardware, construction, or other types of non-research efforts.

Research required to solve a specific operational problem may be procured under the BAA if the primary aim of the project is to do research even though the project result is also used to solve the operational problem. However, planners are advised that the BAA does not preclude use of the normal acquisition process, and they are cautioned that a specific solicitation for a basic research topic under a Request for Proposal (RFP) may be in the best interests of the Government. The CO can, in fact, deny use of the BAA process if the latter appears to be the case.

The "Broad Agency Announcement" for USAMRDC is published annually for general distribution by the USAMRDC AMO. The booklet describes the USAMRDC basic research needs, the criteria for evaluating proposals, and the instructions for preparing and submitting proposals. Supplementary announcements of basic research needs are made in scientific journals, as required.

In general, proposals are submitted to the AMO, screened for military relevance by Research Area Directors (RAD), and reviewed for technical merit by the laboratory/institutes through inhouse and/or peer review groups. Successful proposals are provided to USAMRAA for support through contracts or grants. (see Appendix F Broad Agency Announcement (BAA) Procedures.)

B.4 UNSOLICITED PROPOSALS

An unsolicited proposal is one that is submitted without prior solicitation from the Government. An unsolicited proposal must meet each of the following criteria:

- It must be a written offer to perform research or development work (including feasibility studies and demonstrations.

- It must have been sumbitted to the Government solely on the offeror's own initiative, and without prior formal or informal solicitation.

- It must be an original effort by the offeror in the form of new ideas, which are unique, and because of the offeror's proposal development efforts, a sole source procurement is warranted.

B.5 GRANTS

Grants may be used instead of contracts when appropriate; DoD plans to issue guidance to the Army during fiscal year 1989. Streamlined administrative procedures will also be promulgated in an attempt to increase productivity of researchers.

B.6 SMALL PURCHASES

Although the sealed bidding and negotiation acquisition processes are the desirable approaches to acquisition, they are time consuming and expensive to carry out. For acquisitions of small dollar value, these approaches would not be cost effective. Federal acquisition policies and procedures make available small purchase and other simplified purchase procedures for acquisitions requiring relatively low-cost supplies and services. A small purchase is the acquisition of supplies or services in the amount of $25,000 or less. The acquisition can be made by using one of the following simplified small purchase procedures:

- Purchase orders;
- Imprest funds; or
- Blanket purchase agreements (BPAs);

The CO makes the decision to use small purchase procedures but the PO, during the acquisition planning process, is required to give suggestions and conduct discussions with the acquisition staff concerning approaches to acquisition.

There are some general principles relating to small purchases and small purchase simplified procedures. First, they must be made in an atmosphere of competition. Acquisitions office staff usually have to solicit quotations orally or in writing, to ensure that prices are reasonable.

Second, small purchase procedures must be used in ways that encourage acquisition from small businesses. Small purchase acquisitions of $10,000 or less must be set aside exclusively for small businesses, unless the contracting officer finds that certain exceptional conditions exist. For small purchase acquisitions above $10,000, the regulations require that contracting officers make every effort to solicit quotations from small businesses, small disadvantaged businesses, and organizations from labor surplus areas..

Third, acquisition through small purchase procedures should not be used to circumvent regular acquisition requirements. It is improper, for example, to break down into smaller acquisitions a requirement that will cost an aggregate of more than $25,000 merely to permit the use of small purchase procedures.

Purchase Orders

Purchase orders are offers by the Government to buy supplies or services under specified terms and conditions, the aggregate amount of which does not exceed $25,000. The purchase order is unique in Government acquisition. Bids and proposals are offers by the prospective contractor, and a contract comes into being when the Government accepts that offer. On the other hand, a purchase order is a Government offer that does not become part of a contract until the contractor indicates his acceptance by signing the purchase order document, beginning work or delivering the supplies.

Purchase orders sometimes follow the solicitation of quotations. While solicitations can be made orally, a Request For Quotation (RFQ) is issued for complex or certain other acquisitions. An RFQ solicits information from a prospective contractor about price, and sometimes his approach and capabilities. The response to an RFQ by one organization or individual is not an offer. Rather, it is an informational response that has no legal standing.

Purchase orders are issued on a fixed-price basis. There is only one exception to this--an "unpriced purchase order." This is rare. PO considering their use should seek assistance from the CO.

Imprest Funds

The term Imprest Fund refers to a small cash fund established by an agency finance officer for disbursements in making small cash purchases, typically less than a few hundred dollars. Procedures for using imprest funds are published in FAR, DFARS and AFARS 13.4.

Blanket Purchase Agreement (BPA)

BPAs are an example of an agreement used for filling anticipated repetitive needs for supplies and services. A BPA, in effect, is a charge account with a supplier. It has an overall price limitation that cannot be exceeded by the aggregate of all purchases made under it, unless the limit is raised by the CO. Under a BPA, separate acquisitions are made according to detailed but simple procedures. No one purchase can exceed the small purchase limitation of $25,000. USAMRAA or acquisitions staff at the laboratories or institutes should be contacted for further information.

C. TYPES OF CONTRACTS

The FAR provides for two families of contract types -- fixed-price and cost-reimbursement. Each family consists of variations on the type, but the essential characteristics within each family are the same.

The CO negotiates the type of contract with the prospective contractors. PO need to understand the characteristics of each major contract type because these can significantly affect acquisition planning and contract administration duties.

The contract types differ in two key respects. One difference is the relative amount of risk placed on the Government and on the contractor. The other is the degree of contract management or administration that each type places on the Government.

C.1 FIXED-PRICE CONTRACTS

Although there are several types of fixed-price contracts, the one most commonly used is the firm fixed-price contract. In this type, the contractor agrees to deliver all supplies or services at the times specified and for an agreed upon price that cannot be changed (unless the contract is modified). If the contract price is $100,000 and the contractor spends $125,000, the contractor loses the difference. The contractor must still deliver all that he promised, and the Government need only pay the initially agreed upon price after delivery and acceptance of the supplies or services. On the other hand, if the contractor's cost were only $80,000, he would make a profit of $20,000.

Firm fixed-price contracts place maximum risk on contractors and little or no risk on the Government. The contractor has made a commitment in the contract to deliver as promised in return for the specified consideration. The Government has the right to receive what it bought for the price it promised to pay. If the contractor fails to perform at the contract price, it is liable for a breach of contract that can bring severe additional costs to the contractor.

Because the risk is high to contractors, their incentive to perform according to the terms and conditions of the contract is quite high. Therefore, the Government's contract monitoring requirements are usually far less than those for cost-reimbursement type contracts. COR and PO must still monitor and review contract proposals and perform other contracting administration duties on fixed-price contracts; however, the magnitude of this effort is normally far less than for cost reimbursement type contracts.

If firm fixed-price contracts confer maximum risk on contractors while minimizing Government risk monitoring responsibility, why aren't they usually used for Federal acquisitions? The main reason is that many Government requirements cannot be translated into the definable and clear-cut specifications needed for this kind of contract. For an offeror to prepare a proposal or agree to a fixed-price contract, the specifications must be quite unambiguous and contain little or no uncertainty. If such specifications are possible, then responsible potential contractors are willing and able to develop a fair and reasonably priced offer and to assume a reasonable risk.

Many requirements in the USAMRDC mission, however, cannot be specified with the certainty required for fixed-price contracts. In the absence of this certainty, responsible potential contractors have no way of estimating the price of the work with the degree of accuracy needed for fixed-price contract risk, nor is USAMRDC able to determine the accuracy of the proposed price.

Research and development, demonstrations, the conduct of surveys and studies, and their related requirements are typical examples of work that has too much uncertainty associated with it to be used as the basis for fixed-price contracts. If the Government tried to use a fixed-price contract to meet these needs, it would either result in offers from sources that are not responsible or capable of doing the work, or offers that have astronomically high costs attached to them to cover the great potential risk to contractors.

C.2 COST-REIMBURSEMENT CONTRACTS

Cost-reimbursement contracts, the second family of contract type, are widely used by USAMRDC. Like the fixed-price contract, there are several variations. The most common is the cost-plus-fixed-fee contract, and is used when the uncertainties involved in contract performance are of such magnitude that cost of performance cannot be estimated with sufficient reasonableness to permit use of fixed-price type contracts. Rather than guaranteeing to perform all contract terms and conditions at the specified price, the contractor agrees to deliver its "best efforts" to perform the requirements in return for costs incurred and a reasonable fee. This type of contract provides for negotiations of estimated cost and a payment of a fixed dollar fee to the contractor. This fee cannot be changed unless the scope of work in the contract is changed by the parties to the contract.

Because the contractor cannot specify the exact price of performing, he agrees to a "total estimated cost." This total estimated cost represents the best estimate of both the Government and the contractor, as agreed to in negotiations. It also is a contract cost limitation that the contractor cannot exceed, except at the risk of non-reimbursement. This limit can be changed by mutual agreement of the Government and the contractor through a modification to the contract.

Every cost-reimbursement contract contains a Limitation of Cost clause that limits the contractor from exceeding the total estimated cost. The clause requires the contractor to notify the Government when it expects to reach 75 percent of total estimated costs in the next 60 days. COR and PO should review the Limitation of Cost clause carefully. It spells out the essential nature of cost-reimbursement contracts in terms of contractor performance obligations and cost limitations. For cost-plus-fixed-fee contracts, the Limitation of Cost clause can be found at FAR 52.232-20.

In cost-plus-fixed-fee contracts, the contractor's risk is minimal. He only promises to do his best or "use his best effort" to perform the work. No guarantee is given to the Government. Failure to do the specified work will not be a breach of contract, nor will it cost the contractor any money, so long as he used his best efforts.

The Government's risk is commensurately high. It has no guarantee that it will get the specified work. If the work is not completed and the maximum costs have been reimbursed to the contractor, the Government has two choices, equally unsatisfactory. It can elect not to add funds to the contract and, therefore, not get any further work. Or, it can elect to add money to the contract to fund the remaining work. This latter action is known as "funding the cost overrun".

Cost overruns are a risk of the cost-reimbursement type contract. While overruns are occasionally caused by contractor waste or inefficiency, far more often they are due to the lack of certainty in contract requirements. Given the nature of the work acquired by cost-reimbursement contracts, contractor performance often evolves in ways that neither the contractor nor the Government foresaw at the time of award.

Because of the high Government risk and the lack of guaranteed performance, cost-reimbursement contracts must be monitored far more closely than the fixed-price types. The COR and PO must ensure that the contractor is actually providing his best efforts and that the contractor is judiciously expending funds and controlling cost.

In addition to the cost-plus-fixed-fee contract, there are several other types of cost-reimbursement contracts. Two relatively common variations are:

- **Cost contracts.** These are identical to the cost-plus-fixed-fee contract except they contain no fee. Reimbursement is made only for appropriate costs. This type is usually used for research and development work, particularly with educational or other non-profit institutions.

- **Cost-sharing contracts.** These are cost-reimbursement contracts in which the contractor receives no fee and is reimbursed for only an agreed-upon portion of costs. The contractor, in effect, agrees to share a portion of the costs in expectation of some future gain or benefit.

C.3 GRANTS

Grants may be used to conduct and support basic and applied research and development projects that are necessary to the responsibilities of DoD, relate to weapon systems and other needs, have a principal purpose of transferring a thing of value to the grantee to carry out a public purpose of support or stimulation instead of acquiring property or services for the direct benefit of DoD, and to which substantial involvement between the grantee and DoD is not expected. Specific guidance on the use of grants will be provided as a USAMRDC Standing Operating Procedure (SOP) on the Extramural Program issued by the PARC.

D. METHODS OF FUNDING

Cost reimbursement contracts award an upper limit of funding against which a contractor may draw on the basis of expended effort, delivered items, or the like. There are several methods that may be used to establish those awards. The CO, with recommendation from the PO, may choose:

D.1 FULL FUNDING of the contract in which the funds for the entire research effort are committed to the contractor. There are regulatory, planning and fund disbursement issues that must be considered before making such an award.

D.2 INCREMENTAL FUNDING of a contract in which the total work effort is to be performed over multiple time periods and funds are allotted to cover discernible phases or increments of performance.

The incremental funding technique can only be applied to cost-reimbursement contracts for the acquisition of research and development services and other types of nonpersonal services such as studies and surveys. It shall not be applied to construction services, architect-engineer services, or services subject to the Service Contract Act of 1965, as amended. This funding technique allows for contracts to be awarded for periods in excess of one year, even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award.

D.3 OPTIONS are a provision in a contract under which, for a specified time, the Government may elect to purchase at an established price, or at a price that can be established by reference to some specific method of calculation which will make the price certain, additional quantities of the supplies or services called for by the contract. An option may call for delivery of the option quantity within the initial contract period or may call for delivery of the option quantity subsequent to the initial contract period.

Options are most often used in situations where the Government is indefinite as to the quantities it requires. A contract with an option provision will allow for the purchase of a specified quantity, with the Government retaining the right to purchase a specified further quantity at a set price at some later time.

Option provisions invariably contain a statement to the effect that the Government will notify the contractor within some specified time (e.g., 60 days prior to the expiration date of the contract) of its intent to exercise the option.

The decision to acquire the option quantity is primarily the program officer's. In order to avoid the possibility of losing the Government's right to exercise the option, the PO must notify the CO of this decision in sufficient time to allow the CO to put the contractor on notice within the time specified in the contract.

To exercise an option, revalidation of the requirement as well as market analysis to establish that doing so is in the Government's best interest, may be required. If so, the PO will have a role to play in these functions. The PO is also responsible for providing the funds necessary to pay for the option quantity.

SECTION III. ADVANCE ACQUISITION PLANNING

This chapter and the next outline methods and concerns that are central issues for addressing USAMRDC extramural research and development needs through the negotiated contracting process, a functional outline of which appears as Appendix G, "Solicitation Outline." The focus of the material is on meeting specific needs through the Advance Planning and Request for Proposal (RFP) processes. Coverage of the Broad Agency Announcement (BAA), Intragovernmental Transfer of Funds (ITF), and Grants is generally sufficient only to show the place those funding mechanisms occupy in the extramural research program.

The negotiated contracting process has three discrete phases -- advance procurement planning, soliciting and awarding the contract, and administering an awarded contract. This section is concerned with the first of these -- advance procurement planning. It outlines the basic tasks that the Government must complete before it approaches the business community for proposals. It concentrates on the responsibilities of the PO, although many of these tasks require close cooperation with the CO to be accomplished effectively.

The steps in this first phase of the contracting process are accomplished in a logical sequence for the most part, and are designed to produce several major documents that are needed to carry out the acquisition process. This chapter attempts to follow that sequence in outlining the use and content of the acquisition documents.

A. ADVANCE PLANNING AND SCHEDULING

Planning for an acquisition is the best way of ensuring that the product or service will be acquired in the most efficient, trouble-free manner. This process should begin as soon as a program need is identified and it is obvious that the need must be met outside the USAMRDC. Acquisition planning involves a general consideration of all the elements that will be required in connection with a particular acquisition. This process may be quite simple or very elaborate, depending on the cost, political sensitivity, complexity, or importance of the item or service being acquired. Advance planning helps both the CO and the PO to more efficiently procure outside services by enabling them to allocate and schedule the work involved in an acquisition, and to resolve potential problems early in the process.

Failing to schedule the overall acquisition workload of an office or agency results in an inordinate percentage of contract awards being made in the closing months, weeks, and even days, of the fiscal year. This excessive year-end spending invites increased intervention and scrutiny from Congress, the Office of Management and Budget, and the media. The key to avoiding this is to begin advance procurement planning early to permit contract award at the beginning of the fiscal year.

A.1 CONCEPT DEVELOPMENT

Concept development is the first step in an acquisition. In this phase the agency realizes that an acquisition is necessary and defines in broad terms what this effort will entail. A plan, or concept is evolved which reflects consideration of USAMRDC in-house capabilities, Defense Technical Information Center (DTIC) report holdings, budget realities, and the length and timing features of the acquisition cycle. The CO is an obvious early participant in such planning.

Concept development may include assessment of prior contract results, in-depth literature searches, and discussions with technical and scientific personnel, both within and outside the Government. These discussions may serve to determine interest, scientific approaches, technical capabilities, and the state-of-the-art relevant to the subject area. In holding such discussions with people outside the Government, care must be taken not to disclose advance information on any specific acquisition, proposed or contemplated, because to do so might create the impression that the Government has given the recipient an unfair advantage over other organizations subsequently solicited.

Once the concept has been formulated, it must be reviewed for program relevance, need, merit, priority, and timeliness by the appropriate management staff. In most programs, the concept development phase is intimately connected with the budget process since that is the primary means of identifying, defining, and approving program acquisitions. Although PO may not become involved with an acquisition until after the initial budgeting has been accomplished, they always have to deal with budget considerations.

A.2 MATERIEL ACQUISITION PROCESS

The Army process for conceiving, developing, acquiring and fielding new items of equipment and products is contained in a **Life Cycle System Management Model.** Appendix E is a simplified schematic diagram of the process as it applies to hardware, biologicals and pharmaceutical products The Medical Materiel Acquisition Management Handbook, 30 Sep 86, should be used for instruction and details when actually working the system.

A.3 RESPONSIBILITIES FOR ACQUISITION PLANNING

Acquisition planning is usually done jointly by the PO and the CO. The PARC provides official guidance in the "Procedure for Acquisition Planning" of the Standing Operating Procedures on the Extramural Program, SOP 1.

PO who expect to initiate acquisitions should discuss their requirements with the CO. These discussions should result in understandings on:

- The details of an acquisition plan;
- A schedule for completing an acquisition plan;
- Preliminary discussion on the work statement, specifications, and appropriate evaluation criteria;
- Preliminary discussions on the content and timing of the request for solicitation.

CO are required to coordinate with program personnel to ensure:

- Timely and comprehensive planning for acquisitions;
- Timely initiation of requests for contracts; and
- That program personnel have been instructed in proper acquisition practices and methods.

B. ADVANCE PLANNING ISSUES

Planning documents are administrative tools designed to enable the PO and the CO to identify and accomplish the tasks needed to acquire goods and services within a specified length of time. The documents serve as reference checklists for the acquisition, and as a means for identifying and resolving problems early in the acquisition cycle. The specific name and content of a required planning document depends on the size and type of the proposed acquisition. Irrespective of the formal written requirements, all advance planning should probably address the following basic issues at some time in the process:

B.1 BACKGROUND OF THE ACQUISITION

- **Purpose of the contract.** Briefly describe the general requirements of the contract, including a citation of the legislation that may authorize the program/project.
- **Need.** Discuss the need for the project.
- **Background history.** Describe the background and necessity of the acquisition. Include prior, present, and planned efforts in the program area to which the requested contract is related, as well as in closely related work that has been supported by DOD and other Federal agencies. Identify specific contracts and grants whenever applicable. Describe and give the results of the

literature search conducted on the research topic in the DTIC report holdings.

- **Alternatives to the Acquisition.** Discuss efforts made to determine if existing projects, supplies or materials will satisfy the requirement. Include any in-house efforts, searches and clearinghouse reviews conducted to avoid duplication of effort.

- **Project risk.** Discuss major areas of project risk, including technical, cost, and schedule risk. Describe what efforts are planned to reduce risk. If an acquisition that is planned to be awarded using other than full and open competition represents a significant portion of a proposed contractor's business, discuss the effect on technical capability, schedules, changes in contractor workload, and related effects on cost.

- **Estimated cost.** Give the PO estimate of the total cost to perform the proposed contract and an estimate for individual phases or areas of the work. An estimate of technical staff hours and direct material required to perform the service should be included.

- **Project funding.** Include a summary of funds expected to be obligated for the entire project by fiscal year and phases. Include expenditures for previous years. Discuss the probability of obtaining future-year funding and/or what specific managerial action can be taken to ensure future funding (if applicable).

- **Program Officers.** Identify the program personnel who have key roles in planning the proposed acquisition. At a minimum, give the name, title, full mailing address, and telephone number of a Point of Contact.

B.2 OBJECTIVES OF THE ACQUISITION

- **Statement of Work.** Describe exactly, but succinctly, what is to be done and when it is to be done. (See the section on writing an SOW near the end of this chapter.)

- **Period of performance.** Specify number of months (or other time period) required for total performance and, if appropriate, for each phase of the work. Indicate the proposed starting date and required date of delivery for each deliverable.

- **Reporting/delivery requirements.** Describe the basis for establishing the delivery/reporting requirements and include the anticipated deliverables and time(s) for delivery.

- **Replication, dissemination, or use of the results.** Discuss anticipated replication, dissemination, or use of the results. Describe who will use it, and how it will be used. Include a description of the system for delivering the results.

- **Data, data rights, patents, copyrights and licensing.** Discuss the data to be developed. Specify which data are to be delivered and which data are to remain in the contractor's possession. Discuss how the data are to be used, maintained, disclosed, and disposed of by the contractor. Discuss data that are subject to the Privacy Act or Confidentiality of Information clause. Discuss data to be delivered with limited rights, data where title would not vest in the Government, and anticipated copyrights or patents. Discuss whether or not the data will permit any follow-on acquisitions to be competitive.

- **Phasing.** Briefly describe discrete tasks or stages of accomplishment that are appropriate to phasing. Describe the performance evaluation criteria for each phase before proceeding to the next.

- **Special Terms and Conditions.** Identify or describe any special terms or conditions which should be included in the contract. Human use, animal use and surety material use are but a few of the possibilities in this regard.

B.3 PLAN OF ACTION

- **Sources for solicitation.** Within a particular field of interest, a PO becomes familiar with many potential sources and acquires knowledge of each source's technical capability, physical resources, experiences in a given area, and performance history. It is expected that the PO will use this knowledge to develop a recommended source list. The PO will also use appropriate business/scientific journals to identify new sources. In addition, the CO may advertise for sources in the Commerce Business Daily. In developing a source list, the PO must be careful to avoid improper vendor contacts. Additionally, it is incumbent upon the PO to cooperate with the ADSADBU and CS in identifying viable small and small disadvantaged businesses, and labor surplus areas to which Federal acquisition dollars can be targeted in accordance with statutory set-aside programs and executive orders.

- **Justification for other than full and open competition.** A full explanation of why it is impossible or impractical to obtain competition for the acquisition. If the acquisition is to be sole source, the solicitation request must include a certification that only the one source has the necessary competence or resources to fulfill the contract requirements. The format prescribed by AFARS 6.303-91 for this action is in Appendix A.

- **Post-award administration and monitoring.** Detail milestones that require periodic evaluation of the contractor's progress. Discuss any formal management systems to be used in contract monitoring. Discuss plans for post-award conferences and site visits. Delineate the timing of the periodic status reports.

- **Technical evaluation plans.** Discuss the plans for technical evaluation of the proposal. Give the name, title, full address and telephone number of each evaluator who has agreed to serve as a member of the SSEB. Discuss potential conflict of interest situations.

- **Technical proposal instructions and evaluation criteria.** Include any instructions or information that will help the contractor prepare a technical proposal. Also, outline a system for evaluating technical proposals, the evaluation criteria, and the relative weights assigned to each.

- **Reference material.** List and describe study reports, plans, drawings, and other data to be made available to the contractor for use in preparation of proposals and/or in performance of the contract. Information should also be provided as to whether such material is currently available and, if not, when it will become available.

- **Contract type.** Provide the rationale for recommending a particular type. Explain plans for multiple awards, options and incremental funding.

- **Government furnished material/facilities.** Indicate material and facilities that will be furnished to the contractor and any associated problems that may be encountered. Discuss possible inequities that may arise in furnishing the materials or facilities. Discuss screening efforts for availability of these items through GSA excess-property schedules.

- **Socioeconomic programs.** Discuss preliminary liaison with the ADSADBU to determine if the acquisition is appropriate for the various socioeconomic acquisition programs; i.e., small business, disadvantaged business, or labor surplus area set-asides.

- **Data for future acquisition.** The PO should state whether, at the conclusion of the proposed contract, it is anticipated that another acquisition action will be required. If so, the kinds and amounts of technical data required from the proposed contract should be indicated to assure competition in future acquisitions and to prevent the contractor from becoming a sole source because the Government lacks the data, e.g., drawings, techniques, test results, etc., to permit a full and open competition.

- **CBD Announcement.** Draft a statement which the CO may use to announce the solicitation in the Commerce Business Daily (CBD).

- **Special approvals/coordination/clearances.** Copies of required clearances and approvals should be part of the planning documentation. Areas of concern in this regard are human use, animal use, recombinant DNA actions, etc.

- **Environmental and Safety Considerations.** All acquisition actions must consider and report on the possibility of environmental and safety issues in the work to be supported. Details of this requirement are given in USAMRDC Standing Operating Procedures of the Extramural Program, SOP 2, issued by the PARC.

- **Other considerations, as applicable.** Discuss special contract clauses, if required. Discuss circumstances such as the effect of a protest on a previous acquisition, special public law or regulatory requirements that place restrictions on this acquisition, special geographical restrictions, and use of a special type of synopsis. If necessary, address planned preproposal conference, preaward survey, and preaward site visits.

C. SPECIAL APPROVALS AND CLEARANCES

There are numerous types of acquisitions, or elements within an acquisition, that require particular approvals or clearances. The following special program approvals or clearances should be reviewed to see if they are applicable to the acquisition in question. Those that are applicable must be addressed in the acquisition planning document.

Human Use

Safeguarding the rights and welfare of human subjects participating in research and development supported by contracts, grants and orders awarded by USAMRDC is of utmost concern to the Command.

While this is primarily the responsibility of the contractor or Government agency that is supported by USAMRDC, the sensitivity of such research necessitates that the Command exercise prudent oversight. Accordingly, coordination with the Human Use Review and Regulatory Affairs Office (HURRAO) is essential to complete planning. HURRAO will determine which protocols must be submitted to The Surgeon General's Human Subjects Research Review Board, and arrange for such submissions. (See Appendix B, Use of Humans as Research Subjects in the Extramural Research Program.)

Animal Use

The use of animals is an extremely sensitive issue within and outside the research community in general. Army Regulation 70-18, "The Use of Animals in DoD Research", and the National Institutes of Health publication, "Guide for the Care and Use of Laboratory Animals," prescribe the procedures that must be followed in this matter. Again, while responsibility rests with the contractor, USAMRDC maintains an oversight role which should be considered in acquisition planning and contract administration. (See Appendix C, Research Involving Animals.)

Chemical Surety Materiel

Research involving the use of chemical surety materiel must comply with the safety/surety requirements applicable to the use of dilute, neat or research quantity materiel. Prior to negotiation, a site visit must be performed by a representative of the USAMRDC Safety and Chemical Operations Branch to evaluate and approve the proposed contractor's facilities and procedures for handling surety materiels. Safety and Surety requirements will be set forth in the contract.

Recombinant DNA

Research on recombinant DNA must conform with the policies and procedures in "NIH Guidelines for Research Involving Recombinant DNA Molecules" and its Administrative Supplements. The contract will set forth all of these requirements.

Good Laboratory Practice (GLP) and Current Good Manufacturing Practice (CGMP)

When nonclinical study results are planned in support of a petition to FDA for approval of an investigational new drug or medical device, the contract will require compliance with 21 CFR 58. Contract provisions must also require that USAMRDC be notified of FDA inspections and that the COR has the same access to contractor records as the FDA. When drug and biological drug products are to be delivered for administration to humans, compliance with CGMP 21 CFR 211 is specified in the contract. Contract costs will include compliance costs associated, for example, with storage and retention of data and materials. Contracts for conducting studies relating to health effects, environmental effects, and chemical fate testing shall require compliance with GLP regulations in 40 CFR 792. These regulations should assure the quality and integrity of data submitted pursuant to Section 4(a) of the Toxic Substances Control Act. COR access to research records should be included in the contract.

Paid Advertising

Paid advertisements and notices to be published in newspapers and periodicals may be authorized by the CO in accordance with the requirements and conditions set forth in FAR Subpart 5.5. Requests for advertising must be accompanied by the laboratory commander's written authority to advertise or publish, and give the names of the newspapers or journals, the frequency and dates of proposed advertisements, the estimated cost, and other pertinent information. Paid advertisements should be limited to the publication of essential details of supplementary BAA program announcements and requests for proposals.

Printing

FAR Part 8.801 defines printing as "printing, binding, blank-book, and microform work (including any items requiring the processes of composition, platemaking, presswork, or binding) for use of an executive department, independent agency, or establishment of the Government." The acquisition of printing by contract is prohibited unless it is authorized by the Joint Committee on Printing of the U.S. Congress. Specific procedures to be followed are contained in the Government Printing and Binding Regulations.

Contracts With Federal Employees

Contracts between the Government and Government employees, or between the Government and organizations that are substantially owned or controlled by Government employees may not knowingly be entered into, except for the most compelling reasons (See FAR Subpart 3.6 and 45 CFR 73).

A-76 Review

OMB Circular No. A-76 provides that it is the policy of the Government to rely generally on private commercial sources for supplies and services, if certain criteria are met, while recognizing that some functions are inherently Governmental and must be performed by Government personnel. It also provides that it is Government policy to give appropriate consideration to relative cost in deciding between Government performance and performance under contract. In comparing the costs of Government and contractor performance, the Circular provides that agencies shall base the contractor's cost of performance on firm offers.

The Circular and the Cost Comparison Handbook, Supplement No. 1 to the Circular, prescribe the overall policies and detailed procedures required of all agencies in making cost comparisons between contractor and Government performance. These documents state that in making cost comparisons, agencies shall:

- Prepare an estimate of the cost of Government performance based on the same work statement and level of performance as apply to offerors; and
- Compare the total cost of Government performance to the total cost of contracting with the potentially successful offeror.

These documents further provide that solicitations and synopses of the solicitations issued to obtain offers for comparison purposes shall state that they will not result in a contract if Government performance is determined to be more advantageous. They also state that each cost comparison shall be reviewed by an activity independent of the activity which prepared the cost analysis to ensure conformance with the instructions in the Hand book. Finally, the documents provide that, ordinarily, agencies should not incur the delay and expense of conducting cost comparison studies to justify a Government commercial or industrial activity involving 10 or fewer Full-Time Equivalents (FTEs). Activities below this threshold should be performed by contract unless in-house performance is justified. However, if there is reason to believe that inadequate competition or other factors are causing commercial prices to be unreasonable, a cost comparison study may be conducted. Activities exceeding 10 FTEs shall undergo cost comparisons, unless waived.

D. RESEARCH ACQUISITION PATHS

There are essentially five avenues for acquiring extramural research efforts. All need planning and coordination to ensure attainment of mission goals, but each has somewhat different formal requirements for documentation and approvals. The presolicitation phase for each of these avenues is briefly outlined below. Detailed descriptions and requirements may be found in the appropriate USAMRDC Procedure.

Intragovernmental Transfer of Funds (ITF) are acquisitions not subject to the provisions of the FAR. They are included in the listing because they are a major USAMRDC research investment.

D.1 ACQUISITION PLANNING

- Program personnel identify the need for a solicitation.
- Program personnel and the CO coordinate to produce an Acquisition Requirements Package (ARP) comprised of:

-- An Acquisition Plan which addresses all advance planning issues required by FAR, DFAR and AFAR 7.1.

-- A Source Selection Plan which describes the methods to be used for the solicitation and award. (See USAMRDC Standing Operating Procedures on the Extramural Program, SOP 4.)

-- A USAMRDC Form 9 which presents the balance of the planning documentation outlined in Appendix G of this Guide.

D.2 BROAD AGENCY ANNOUNCEMENT

- Program personnel identify research topics that can be supported under the BAA.
- The RAD sends a statement on those research needs to the Acquisition Management Office (ACQ) for insertion in the **BROAD AGENCY ANNOUNCEMENT**, published annually by ACQ.
- The Broad Agency Announcement is distributed openly and widely outside the Government. (Copies for reference are available to USAMRDC personnel.)

D.3 INTRAGOVERNMENTAL TRANSFER OF FUNDS

- Generally, research needs are established by USAMRDC planners, working directly with representatives of other Government agencies. Unlike the situation with regard to acquisitions outside the Government, there are no legal restrictions on discussions and planning for projects to be supported by the Intragovernmental Transfer of Funds. Appendix M to this Guide discusses these projects.
- The procurement is initiated by submitting a USAMRDC Form 9 to the Acquisition Management Office. The Form 9 should spell out reporting requirements, etc, just as is done for a contract recommendation.

D.4 GRANTS

- The advance planning for Grants support is handled in the same fashion as for contracts.
- Grants are solicited through the BAA, not specific RFPs.

E. THE STATEMENT OF WORK

The statement of work (SOW) is probably the single most critical document in the acquisition process. It describes the work to be performed or the services to be rendered, defines the respective responsibilities of the Government and the contractor, and provides an objective measure so that both the Government and the contractor will know when the work is complete and payment is justified.

The SOW must be precisely worded because it will be read and interpreted by a variety of people, such as attorneys, acquisition personnel, cost estimators, accountants, technical specialists, etc. If the SOW does not state exactly what is wanted, or does not state it precisely, it will generate contract management problems for both the PO and the CO. Oftentimes, there is a tendency to assume that prospective contractors are as knowledgeable as those who have drafted the SOW, and that their terminology is the same as the Government writers. Ambiguous statements of work often result in unsatisfactory contractor performance, delays, disputes, and higher contract costs. (See Appendix N, Hints for Writing Statements of Work.)

Statements of work are sometimes referred to administrative boards or the courts for interpretation. These interpretations represent what an objective third party thinks is the intention of the document. Generally speaking, the court or board will not concern itself with what the drafter **intended** to express, but will look at what **was** expressed. This determination is usually made solely on the basis of the words used and the context in which they appear.

How the statement of work is written affects the entire acquisition cycle. It determines the type of contract that is awarded, it influences the number and quality of proposals received, and it serves as a baseline against which to evaluate proposals, and later, contractor performance. Thus, the SOW is the key element in shaping and directing all three stages of the acquisition cycle: advance procurement planning, solicitation and contract award, and post-award administration.

In the advance planning phase, the SOW establishes the parameters of the Government's requirements so that the PO and CO can determine the best way to accomplish them. Therefore, the SOW must articulate program objectives. It must also establish actual minimum requirements for performance of the proposed work.

In the solicitation and award phase, the SOW is the vehicle that communicates the Government's requirements to prospective offerors. At this stage, the SOW guides the offerors on the content of their technical proposals. When a contract is awarded, the SOW becomes part of the contract between the two parties, stating what has been offered by the proposer and accepted by the Government. Therefore, the statement of work defines the scope of work, including tasks the contractor must undertake, types or stages of work, number and type of personnel, sequence of effort, and reporting requirements. The SOW must also establish a guide for technical evaluation of the proposals. Both the offeror and the evaluators need a list of factors that clearly state how the agency will compare the offers. The technical evaluation criteria are not part of the SOW itself but, because they relate directly to the requirements specified in the SOW, they must be carefully considered when preparing it.

At the post-award stage, the SOW provides the mechanism for defining the work or products that are to be produced and the deadlines for producing them. To be effective at this stage, the SOW should provide a guide for monitoring the progress of work by specifying what products should be delivered or task accomplished at specific times during the course of the contract. The SOW also should describe the products to result from the work effort and set the standards of contractor performance.

E.1 COMMON ELEMENTS OF STATEMENTS OF WORK

Because each acquisition is unique, each SOW must be tailored to the specifics of the project. The elements of a SOW will vary with the objective complexity, size, and nature of the acquisition. In general, it should cover the following matters, as appropriate.

Background. This section describes the requirements in general, non-technical terms. The narrative should explain why the acquisition is being pursued and how it relates to past, current, or future projects. Include a summary of statutory program authority and any regulations that are applicable. If any techniques have been tried and been found to be effective, they should be included here.

Project Objectives. This section should be a succinct statement of the purpose of the acquisition. It should outline the results that the Government expects and may also identify the benefit to the program that is contemplated.

Scope of Work. This section provides an overall, non-technical description of the work to be performed. It expands on the project objectives, but does not attempt to detail all of the work required. This section identifies and summarizes the various phases of the project, and defines its limits in terms of specific objectives, time, special provisions, or limitations. It must be consistent with the detailed requirements. Contractor responsibilities are often summarized here, as are the results or products expected.

Detailed Technical Requirements. This is the section that spells out most precisely what is expected of the contractor in the performance of the work. It describes the specific tasks and phases of the work and specifies the total effort each task or phase is to receive. Considerations that may guide the contractor in its analysis, design, or experimentation on the designated problems should also be included here.

It is important that work statements contain the general language that "the contractor shall furnish the necessary personnel and facilities to .....", as well as the statement of the specific work to be done. This statement is desirable to show that there is more involved in the contract than the mere performance of services. This would be applicable primarily in contracts where there is no end product to be delivered and where the language can be used to demonstrate that the contract is for the work of a contractor's organization rather than a personal services contract.

This section identifies the requirements (i.e. training, computer modeling, tests, verification, etc), and indicates the scope of each. It gives the parameters of tests, for example, and the criteria governing the number of designs, performance, numbers of tests, etc. It also identifies any budgetary, environmental, or other constraints. If more than one approach is possible and the Government prefers a particular approach, it should be identified here. If applicable, this section should also state the criteria on which a choice of alternative approaches will be based.

If end products or deliverables will be required under the contract, they should be clearly and firmly defined here, and the criteria for acceptance should be given. Delivery or completion schedules are expressed either by calendar date or as a certain number of days from the date of contract award. When using the latter method, specify whether work days or calendar days are meant.

Reporting Schedule. This section of the SOW specifies how the contractor shows that it has fulfilled its obligations. It defines the mechanism by which the contractor can demonstrate progress and compliance with the requirements, and present any problems it may have encountered. This is usually accomplished through monthly or bi-monthly progress reports. This section should discuss what areas the reports are to cover, the format, the criteria to be used in accepting reports, the number of copies the contractor should submit, and to whom they should be submitted.

It is important to require the preparation and submission of technical and financial progress reports to reflect contractor certification of satisfactory progress. If possible, the reports should be coordinated to provide a correlation between costs incurred and the state of contract completion.

A **Contract Data Requirements List,** DD Form 1423, is utilized to acquire all data under a contract for materiel acquisition, unless the only deliverables under the development contract are reports. The Form shall list essential data needed, and all items are selectively tailored to the acquisition. The appropriate Project Management office in the US Army Medical Materiel Development Agency (USAMMDA) will ensure that required data is specified in the solicitation and contract.

Special Considerations. This section can be included if there is any information that does not fit neatly or logically into one of the other sections. For example, it may be used to explain any special relationships between the contractor and other contractors working for the Government.

References. This section provides a detailed list and description of any studies, reports, and other data referred to elsewhere in the statement of work. Each document should be properly described, cited, and cross-referenced to the applicable part of the work statement. If documents are limited or hard to get, and will not be attached to the request for proposal, this section should tell where they can be obtained, or when and where they will be available for review. Examples of references include: field memoranda, technical reports, scholarly studies, articles, specifications, and standards.

Key personnel clauses. In some cases, particularly research and study contracts, the work is to be done by specific employees of the contractor. In order to assure that this is done within the limits of availability of such employees, it is common practice to use key personnel clauses. Since the clause is a rather severe restriction on contractor flexibility, it should be used only in cases where the designated personnel are considered essential to the performance of the work. The following is one example of such a clause:

> "The Principal Investigator for this contract is ________________________________, and this individual shall be continuously responsible for the conduct of the research project and closely involved with the research efforts. The contractor shall obtain the CO approval to change the PI, or to continue the research work during a continuous period in excess of three (3) months without participation of an approved PI. The contractor shall advise the CO if the PI will, or plans to devote substantially less effort to the work than estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to or substituted on the research project.
>
> The contractor agrees to assign to any task those key personnel whose resumes were submitted with his proposal who are necessary to fill the requirements of the task.

No substitutions shall be made except in accordance with this clause.

The contractor agrees that during the first ninety (90) days of the contract performance period no personnel substitutions will be made unless such substitutions are necessitated by an individual's sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the contracting officer and provide the information required by next paragraph. After the initial 90-day period, all proposed substitutions must be submitted, in writing, to the contracting officer at least fifteen (15) days in advance of the proposed substitutions, and provide the information required by the paragraph below.

All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitutions, a complete resume for the proposed substitute, and any other information requested by the contracting officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes must have qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of approval or disapproval thereof.

The contractor further agrees to include the substance of this clause in any subcontract which he awards under this contract.

E.2 STEPS IN WRITING A STATEMENT OF WORK

Because the statement of work is the most influential document in an acquisition, it must be carefully planned and written. It expresses what the contractor is to accomplish and determines whether the Government receives the product or service it needs.

Planning the Statement of Work

Carefully planning the statement of work will save time in the writing phase and will make it possible to develop a concise, trouble-free RFP. The first step is to determine the project's objectives. This involves developing clear statements about why the agency is undertaking the acquisition, and what it hopes to achieve. Such a statement is critical because it is impossible to communicate a requirement to potential offerors unless the need can be clearly stated.

Once the project's objectives have been stated clearly in writing, the next step is to meet with the contract specialist, who will help lay out the requirements for the acquisition and the schedule that must be met if a contract is to be awarded by a specific date. The contract specialist can also identify sources of information on regulations and contracting, as well as in-house experts who may be able to help.

The next step is to determine all of the individual requirements that must be accomplished if the agency is to meet its objectives. Requirements that need to be considered at this stage include:

- Deliverables
    - What products/services are required?
    - Who will use the products and how?
- Standards of Performance
    - What performance/accuracy standards can be specified for the products or services?
- Personnel
    - What categories of staff should conduct the project for the contractor?
    - What should be their qualifications?
    - What should be the qualifications/experience of the contractor?
- Methodology
    - What is the appropriate methodology?
    - Are there different possible methodologies?
    - What stages/phases can the project be broken into?
- Schedule
    - When are the results of the project needed?
    - How long should the project take?
    - What is the schedule for the deliverables?
- Location
    - Where should the project take place?
    - Will travel be required?

Once all of the requirements have been listed, they can be arranged into a logical sequence.

During the process of listing the requirements, it may be helpful to do some background reading. Collect and analyze previous documents and contract deliverables that bear on the requirements, including:

- Documents that discuss overall program goals and objectives;

- Reports, manuals, or other deliverables produced in the past; and
- Statements of work developed for similar projects.

Review government-wide or departmental regulations, policy directives, or administrative memoranda that apply to the type of acquisition under consideration. Consult with other program personnel to elicit views on the project, its objectives and requirements.

At this stage, it is important to decide if the complexity of the project requires advice from technical specialists or help from additional writers. If so, identify the personnel needed and specify the areas that each should address.

Specifying the Contractual Approach

Once the project objectives have been clearly stated and the requirements listed, it becomes possible to begin specifying the contractual approach. This process will require a number of decisions:

- Whether the work statement is a design specification, a performance specification, or a combination;
- Whether a completion contract or a level-of-effort contract is contemplated; and
- Whether or not phasing is appropriate.

Each of these decisions will be discussed in more detail below, but as these decisions are being made, a few points should be kept in mind. The objectives of a proposed project will affect the amount of flexibility the contractor will be allowed in designing an approach to the work. A statement of work may be broad and general, or specific and detailed. But whether a statement of work is loose or tight, simple or complex, certain general principals apply:

- The SOW should neither be so narrow as to restrict the contractor's efforts nor so broad as to permit the contractor to explore or undertake work in areas having little relationship to the particular contract tasks.
- The SOW must define the contractor's obligations and be definitive enough to protect the Government's interests.
- The SOW should give the contractor sufficient guidance to be able to perform the work required. The SOW should provide a clear, unambiguous, and complete basis for effective and efficient performance.

Performance Specifications versus Design Specifications

A work statement may be a design specification, performance specification, or a combination of both. A design specification describes the specific materials, parameters, and methods a contractor is to use in delivering a project or service to the Government. The Government is responsible for the results. The contractor must follow the specified steps, but the Government is responsible for ensuring that following these steps will produce the desired result. For example, if the Government issues a design specification for a testing program, the contractor would be responsible for implementing the program but not for the validity or usefulness of the test results.

A performance specification, on the other hand, does not limit a contractor to providing a specific product or service, but rather describes what the contractor must do, what form this effort must take, and the constraints placed on the effort. Performance work statements tell the contractor the objectives to be accomplished, the end goal, or the desired achievement. For example, a performance work statement for a training course might specify the skills to be taught and the level of skill that participants are to achieve. It is then the contractor's responsibility to specify in its proposal how these objectives will be accomplished.

As a general rule, it is best to place maximum responsibility for performance on the contractor, because the contractor is being hired for its expertise and ability to perform. However, the cost of the contract may be higher if the contractor must determine the proper approach and methods. Consequently, if the program office or agency believes it knows a good method for accomplishing its objectives, the cost benefit of specifying this method in the SOW should be weighed against the risk that contractors may know even better methods.

Often work statements use a combination of design and performance specifications. If a decision is made to use such a combination, the Government must be certain that by adhering to the Government's specifications, the contractor can achieve the required result.

Term versus Completion Statements of Work

Careful distinctions must be drawn in the SOW between a term or level-of-effort acquisition and a completion acquisition. Term contracts require that the contractor furnish a report on technical effort during a specified period of time, while completion contracts often require the contractor to develop a tangible end item that is designed to meet specific performance characteristics.

A term or level-of-effort SOW is appropriate for research where the Government is seeking to discover the feasibility of later development, or to gather general information. A term or level-of-effort SOW may only require that a specific number of labor-hours be expended on a particular course of research, or that a certain number of tests be run, without reference to any intended conclusion. For example, a level-of-effort contract might entail providing a certain level of maintenance services and providing technical support.

A completion-type SOW is appropriate to development work where the feasibility of producing an end item is already known. Completion-type SOW may describe what is to be achieved through the contracted effort--such as the development of new methods, new end items, or other tangible results. For example, a completion requirement might entail delivering a final study report, submitting test results, or developing and delivering documentation on a computer program.

Whichever method is selected, the SOW should be definitive and precise. In describing an end item, for example, be specific about the characteristics it must possess and the standards it must meet. In a level-of-effort SOW, where results of the effort are not measurable, be specific about the goals and directions toward which the contractor is to deploy resources.

Phasing

Individual research, development, or demonstration projects frequently lie well beyond the present state of the art and entail procedures and techniques of great complexity and difficulty. Under these circumstances, a contractor, no matter how carefully selected, may be unable to deliver the desired result. Moreover, the job of evaluating the contractor's progress is often difficult. Such a contract is frequently divided into stages, or phases of accomplishment, each of which must be completed and approved before the contractor may proceed to the next. When phases of work can be identified, the SOW should provide for phasing and the RFP will require the submission of proposed costs by phases. The resultant contract will reflect costs by phases, require the contractor to identify incurred costs by phases, establish delivery schedules by phases, and require the written acceptance of each phase.

Phasing makes it necessary to develop methods and controls, including reporting requirements for each phase of the contract and criteria for evaluation of the reports submitted, that will provide, at the earliest possible time, appropriate data for making decisions relative to all phases. A phased contract may include stages of accomplishment such as research, development, and demonstration. Within each phase, there may be a number of tasks that should be included in the SOW.

Phasing should not be used for projects where several tasks must proceed simultaneously because if each task is made a separate phase, progress will be blocked by lack of data.

Outlining and Writing the Statement of Work

Once the individual requirements for accomplishing the project objectives have been clearly stated, and the contractual approach has been specified, the next step is to outline the SOW. An outline provides a structure for the document and saves a great deal of writing time. A detailed outline makes it easier to focus on content and to spot inconsistencies, redundancies, and gaps that may need to be filled. It saves time in the writing phase by providing a clear picture of the inter-relationship among ideas, and the most logical order to present them.

Once the outline has been completed, write a first draft. Remember that the purpose is not to create an entertaining piece of literature, but to express a need and state requirements so that a contractor can understand and respond to them. The next section of this chapter gives specific suggestions for ensuring that the SOW is clear. In general, however, the object in writing a first draft is to get the ideas down on paper. Follow the outline, and write one part at a time. Write as much as possible at a time, but don't try to revise the first draft as it is being written. Include enough detail to communicate clearly with the reader. Explain and illustrate points wherever it is necessary to convey the correct meaning.

Revising the Statement of Work

When the first draft is complete, it will need to be rewritten and revised. The writer should read the SOW several times with a view to revising it. The first time, check only the content:

- Does it contain sufficient information?
- Are more examples needed?
- Are the sources the best obtainable?
- Has too much material been included?
- Is the writing based on sound reasoning?

The second time through, check the effectiveness of the organization:

- Is the subject stated clearly?
- Is the subject advanced in clear stages?
- Is the connection between the stages clear?

During the third reading check the sentence structure and grammar. The next section of this chapter provides suggestions on what to look for during the third reading and some pitfalls to avoid.

Revise the SOW, read it again, and continue this process until it is logical and readable, conveys exactly what is required of the contractor, and emphasizes the critical elements. One of the best ways of determining if an SOW meets these design objectives is to have it reviewed by someone else in the program office. Writers often have trouble critiquing their own writing because they tend to read into their own work what they intended it to say, instead of what it actually says. By all means, get the CO to read the early SOW drafts.

Government Obligations. Care should be taken in describing what the Government is supposed to do. Frequently the contractor's obligation to perform will depend on what the Government does first. If the Government does not perform its part, the contractor will be excused from performing. If it appears that the Government has not performed, then the contractor will have the foundation for an excuse, even if the Government has done its part. This situation may arise when it is not sufficiently clear what the Government is to do and when.

As an example, the phrase, "Based on information supplied by the Government, the contractor shall..." leaves open what information the Government should supply. It could be a great deal; it could be very little. There is no way of knowing whether it is significant or not; costly or inexpensive. There is no way of determining when the Government has supplied this information. But the contractor is in a position at any time to claim that, whatever it was, the firm did not have it. Furthermore, the contractor is in a position to claim that even if it did get it, it did not get it soon enough. Tell precisely the kind of information the Government will supply, and when. Limit the obligation to supplying information or services that are readily available to the Government. Do not agree to give information or services that the Government does not have or that may cost a great deal to get.

F. INDEPENDENT GOVERNMENT COST ESTIMATES

F.1 GENERAL INFORMATION

Contractors responding to an RFP must submit a cost proposal in addition to a technical proposal. Although the acquisition process is designed to ensure price competition, the PO needs to make sure that the prices offered are within the range that the program has budgeted for a particular acquisition. Therefore, the Government requires that an "Independent Government Estimate of Costs" be submitted by the PO as part of the request for contract. This document is the Government's assessment of the probable cost of the supplies or services to be acquired. It assures that program funds are available for the acquisition, assists in the assessment of the utility and cost of individual tasks as they relate to the overall project, and serves as a basis for determining the reasonableness of an offeror's proposed costs and understanding of the RFP.

F.2 STEPS IN DEVELOPING INDEPENDENT COST ESTIMATES

Detailed cost estimates should be prepared by the PO, although the CO can often help with advice on approximate overhead and General and Administrative rates. A Baseline Cost Estimate is developed for the materiel acquisition process. Procedures are described in the **Medical Materiel Acquisition Management Handbook, 30 Sep 86.**

The following step-by-step procedure may be used in developing detailed cost estimates for research projects. Since the SOW has been written first, several of these steps will already have been accomplished.

- Divide the effort into identifiable tasks or logical steps.
- List the categories of labor that will be required in each task or step, i.e., clerical, engineer, research scientist, engineer, etc. In a "level of effort" acquisition, it is necessary to consider, in as much detail as possible, the categories of expertise desired and the training and experience that will be required for each category. This will yield a more accurate estimate.
- Estimate the per-day or per-month cost of each category of labor.
- Estimate the total effort from each labor category by task in terms of person-days or person months.
- Multiply the number of person days or months in each category by the estimate of time required. This will yield the estimated direct labor cost.
- Estimate the amount and type of materials and supplies that will be required and the cost of each.
- Estimate the type and cost of equipment that may have to be purchased through the contract.

- Estimate the type and cost of equipment that may have to be purchased through the contract.
- Identify any other elements of direct cost that the acquisition may require, such as consultant services, computer rentals, etc., and estimate the cost of these.
- Estimate the travel requirements, if any. Identify the destinations, the number of people involved, the length of each trip, and the total number of trips anticipated. Use this information to estimate the cost of this travel in terms of both transportation and per diem.
- If a subcontractor will be required, identify the tasks to be subcontracted and estimate the cost.
- Estimate the amount of overhead that will be charged.

G. TECHNICAL EVALUATION PLANNING

G.1 PLANNING FOR THE TECHNICAL EVALUATION OF PROPOSALS

The SOW and the technical evaluation criteria, taken together, establish the ground rules for an acquisition.

The SOW states precisely what products or services the Government is requesting, while the technical evaluation criteria clearly state the factors that will be used in evaluating the proposals and the relative importance of each. It is important to plan the technical evaluation criteria while writing the SOW because these two parts of the RFP are intimately connected.

Developing a SOW requires that the PO identify project objectives and the actual functions required to accomplish them. Choosing and weighting the evaluation criteria requires that this process be taken one step further--the PO must identify the characteristics or attributes that are required to perform the functions necessary to accomplish the project objectives. Because every contract is different, it is important that the PO take the time to identify those technical attributes of an offeror that will be important in predicting whether or not the required work will be accomplished with the highest degree of quality.

G.2 PURPOSE OF TECHNICAL EVALUATION CRITERIA

Evaluation criteria facilitate an objective assessment of the merits of individual proposals against standards, rather than against other proposals. Each RFP must identify the specific evaluation criteria and the relative importance of the criterion used, so that prospective offerors may judge the basis by which their proposals are to be evaluated, and how they may best devote their efforts in preparing their proposals. Criteria should be definable in specific qualitative terms that are readily understandable by both the offerors and the evaluators.

Development of evaluation criteria and the assignment of their relative importance require the exercise of judgement on a case-by-case basis because they must be tailored to the requirements of the individual acquisition. Because the criteria will serve as a standard against which all proposals will be evaluated, it is imperative that they be chosen carefully to emphasize those factors considered to be critical in the selection of a contractor.

The final evaluation criteria and the indications of their relative importance, as included in the RFP, cannot be changed except by a formal amendment to the RFP issued by the CO. No factors other than those set forth in the RFP can be used in the evaluation of proposals.

G.3 SELECTING AND DEVELOPING EVALUATION CRITERIA

Evaluation criteria must be clear, concise, and fair so that all potential offerors are fully aware of the basis for proposal evaluation and are given an equal opportunity to compete. All evaluation criteria should have the following attributes:

- They should be described in sufficient detail to provide the offerors (and evaluators) with a total understanding of the factors to be used in the evaluation process.
- They should address the key programmatic concerns that the offerors must be aware of in preparing proposals.
- They must be specifically applicable to the acquisition. They should not merely be restatement of criteria from previous acquisitions.
- They should be selected to represent only the significant areas of importance that must be emphasized, rather than a multitude of factors. (All criteria tend to lose importance if too many are included. Using too many criteria will prove as detrimental as using too few.)

Typical examples of topics that form a basis for the development of evaluation criteria are listed below. These examples are intended to help PO develop actual evaluation criteria for a specific acquisition and should only be used if they are applicable to that acquisition.

- Understanding of the problem and statement of work;
- Method of accomplishing the objectives and intent of the statement of work;

- Soundness of the scientific or technical approach for executing the requirements of the statement of work (to include, when applicable, preliminary layouts, sketches, diagrams, other graphic representations, calculations, curves, and other data necessary for presentation, substantiation, justification, or understanding of the approach);
- Special technical factors, such as experience or pertinent novel ideas in the specific branch of science or technology involved;
- Feasibility and/or practicality of successfully accomplishing the requirements (to include a statement and discussion of anticipated major difficulties and problem areas and recommended approaches for their resolution);
- Availability of required special research, tests, and other equipment or facilities;
- The managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources, and to successfully manage the project, including subcontractor and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous experience.
- Availability, qualifications, experience, education, and competence of professional, technical, and other personnel, to include proposed subcontractors and consultants (as evidenced by resumes, endorsements, and explanations of previous efforts); and
- Soundness of the proposed staff time or labor hours, propriety of personnel classifications (professional, technical, others), necessity for type and quantity of material and facilities proposed, validity of proposed subcontracting, and necessity of proposed travel.

G.4 WEIGHTING CRITERIA

A statement or indication of the relative importance must be assigned to each evaluation criterion to inform prospective offerors (and evaluators) of the specific significance of each criterion in comparison to the other criteria. Similarly, if a criterion is subdivided into parts, each of the parts must be assigned a statement or indication of the relative importance. Numerical weights may be applied for use by evaluators, but they may not be included in the RFP.

G.5 COST AS A CRITERION

Cost or price is not generally included as one of the evaluation criteria and is not assigned an indication of relative importance or weight. However, a statement must be included in the RFP to reflect the relationship of cost or price in comparison to the other criteria. The CO must ensure that this statement accurately reflects the appropriate balance between cost or price and the technical factors. The CO and PO should work together in arriving at the final determination regarding the relationship. The following is an example of a statement that may be used to reflect this relationship:

> "Estimated costs shall receive less consideration than technical merit, except in the case where two or more proposals are deemed essentially equal in technical merit. Proposals that are unrealistic in terms of technical goals, schedule commitments, or estimated costs will be deemed reflective of an inherent lack of technical competence or indicative of failure to comprehend the complexity and risks of the contract requirements, and may be grounds for rejection of the proposal."

G.6 SAMPLE EVALUATION CRITERIA FORMAT

The format that follows is for general guidance and should be varied to suit the requirements for each individual project. The items identified may be expanded or modified to reflect technical factors considered to be critical to the specific acquisition.

SAMPLE FORMAT

UNDERSTANDING OF THE PROBLEM

Provides a comprehensive statement of the problem, scope and purpose of the project to demonstrate your complete understanding of the intent and requirements. This understanding indicates a clear awareness of the contract objectives.

SOUNDNESS OF APPROACH

Proposal describes the proposed approach to comply with each of the requirements specified in the Statement of Work. The proposal is consistent with the stated goals and objectives. The proposed approach of assuring the achievement of timely and acceptable performance is well documented and sound. Milestone and/or phasing charts illustrate a logical sequence of proposed events.

PERSONNEL

The staff is competent and experienced in the skills required in the Statement of Work. Resumes of staff and consultants reflect not only academic qualifications but length and variety of experience in similar tasks and clearly demonstrate relevant training and experience. If subcontractors are proposed, information is provided to support the qualifications of the subcontractors.

Information is provided as to which key personnel will be used on this project. Documentation is provided on the decision-making authority of the project director as related to other elements of the organization. The percentage of time each staff member will contribute to the program is adequately identified. The extent to which outside consultants or specialists will be used is documented and evidence of their availability is provided.

FACILITIES

A description and location of the organization's research, test, and other facilities to be used on this project must be provided. Award will be made to that responsible offeror who can best perform the required work in a manner most advantageous to the Government, considering cost and all of the above factors.

G.7 EVALUATION WORKSHEET

Members of an SSEB must report their individual evaluations of every proposal in a solicitation in writing. An Evaluation Worksheet is designed by the PO for that purpose. While there is no standard format for the worksheet, the design must reflect several important considerations if the worksheet is to be useful as a discriminator between proposers.

- The evaluation criteria must be the same as those outlined in the solicitation.

- The worksheet should be laid out in a simple, easy-to-use format. Except for special cases, the evaluation should be on a single sheet.

- Spaces for evaluator comments is important. Comments or impressions jotted down during the evaluation often provide information for decisions, negotiation factors, etc.

- The worksheet should present a word description of the numerical scores so that some common ground may be established among the evaluators.

- Keep the scoring process realistic and simple. Especially when dealing with a large number of proposals, the evaluators can probably do a better job using a method based on just three or four possible scores in each category.

A sample Evaluation Worksheet which encompasses these considerations is shown in Appendix D.

H. SOLICITATION SCHEDULE

When the Advance Planning is completed and documented, the PO and the CO should establish realistic solicitation milestone dates that meet the program needs for award, and that assure timely delivery or completion of the project. Scheduling considerations include:

- Individual PO and CO work-loads;
- Planned, extended absences of either from the office;
- Schedules that are consonant with established office goals for overall orderly and balanced workloads.

The PO should realize that the work confronting the CO in the Solicitation and Award phase of the acquisition process is extensive and time-consuming, and relies heavily on the quality of the Advance Planning. A number of Solicitation and Award considerations are covered in the next Section and outlined in Appendix F.

The elapsed time from the point at which USAMRAA receives the complete Acquisition Requirements Package until award of contract is referred to as the Procurement Action Lead Time (PALT). Standard lead times for USAMRAA are shown below. They are important to bear in mind as a planning factor.

USAMRAA STANDARD PROCUREMENT ACTION LEAD TIMES

Type of Contract/Cost	
Other than full and open competition	
$50,000 to $100,000	90
Over $100,000	180
Over $1,000,000	240
Over $10,000,000	300

Full and open competition

$50,000 to $100,000 ------------------------ 160

Over $100,000 ------------------------------ 250

I. CONTRACTING FOR DEVELOPMENT

Development-type contracts are very expensive and very complex. Planning issues include most of what has been covered in this section, and more. Human use, Good Laboratory Practices, NDA phase reports, involved deliveries, and close monitorship of the contract efforts are a few of the rather unique issues confronting the development PO, CO and COR.

A full coverage of the development acquisition process is beyond the scope of this Guide. The interested reader is referred to Appendix E and Appendix H for a preliminary overview of the process, and to the Medical Materiel Acquisition Management Handbook for details.

SECTION IV. SOLICITATION AND AWARD

The Federal Government uses different methods and approaches to acquire goods and services. These acquisition methods and approaches, their differences and similarities, are discussed in Section II of this guide.

Contracting by negotiation is the most commonly used approach in USAMRDC. It is also the most complex and places the most demands on the PO. In this contracting approach, the Government communicates its requirements to the business community by means of a solicitation document known as a Request for Proposal (RFP). In addition to the SOW discussed in the previous section, this document contains various representations and/or certifications to be completed by prospective contractors, as well as the proposed terms and conditions of the resulting contract. Also included are instructions to offerors to guide them in preparing their proposals, and information telling offerors how the Government will evaluate proposals to determine which offer will be selected for contract award.

The primary responsibility shifts to the CO during most aspects of the solicitation and award phase of an acquisition. The PO plays more of a supporting role at this stage. This section gives a detailed outline of the project during solicitation and award.

A. THE REQUEST FOR PROPOSAL (RFP)

The purpose of the RFP is to convey information that prospective offerors need in order to prepare a proposal. The RFP describes all the information that prospective offerors must furnish to permit a meaningful and equitable evaluation of their offers. The RFP must be clear, complete, accurate, and consistent with the requirements of the acquisition so that it provides all who receive it with the same understanding of the requirements.

The CO is responsible for preparing the RFP with the assistance of the PO. Much of the information in the RFP is derived directly from the planning and other solicitation materials furnished by the PO. As a rule, the CO does not have the technical knowledge to uncover or correct any substantive deficiencies that may exist in the technical data. Therefore, the PO must take care to develop supporting documentation that will fully satisfy program needs and objectives when included in the RFP. The PO should review the final RFP before it is printed and released. In turn, the CO shall provide the PO with a copy of the RFP and the CBD announcement at the time they are issued.

The RFP should meet the following objectives:

- The SOW must clearly specify the work to be done by the contractor.

- The general, technical, and business instructions must contain all the essential information prospective offerors need to prepare their proposals.

- The evaluation criteria must clearly indicate the technical, management, personnel, and cost or pricing factors that are to be the major considerations in selecting the successful offeror.

- The RFP usually requires that proposals be submitted in two parts--a "technical proposal" and a "business proposal." Each part is to be separate and complete in itself so that one may be evaluated independently of the other.

- The technical and business proposal instructions must provide all the information deemed essential for proper evaluation of the proposals so that all prospective offerors are aware of all requirements, and so that differences in proposals will reflect each offeror's individual approach to the requirements, not different interpretations of the requirements.

The RFP must inform prospective offerors of all evaluation criteria and of the relative importance attached to each criterion. Evaluation criteria must be described sufficiently enough in the RFP to inform prospective offerors of the significant matters that should be addressed in the proposals. Only the evaluation criteria set forth in the RFP can be used in evaluating proposals; these criteria can only be modified by a formal amendment to the RFP.

Generally, the RFP will provide that the technical proposal omit any reference to cost. However, resource information, such as data concerning labor hours and categories, materials, subcontracts, travel, computer time, etc., must be included in the technical proposal so that the offeror's understanding of the scope of work may be evaluated.

A.1 UNIFORM CONTRACT FORMAT

The FAR requires CO to use the Uniform Contract Format in preparing both RFPs and contracts. This format, outlined on the next page, makes it easier for the Government to prepare RFPs and contracts, and for offerors and contractors to follow these documents.

UNIFORM CONTRACT FORMAT

Part I - The Schedule

A	Solicitation/contract form
B	Supplies or services and prices/costs
C	Description/specifications/work statement
D	Packaging and marking
E	Inspection acceptance
F	Deliveries or performance
G	Contract administration data
H	Special contract requirements

Part II - Contract Clauses

I	Contract clauses

Part III - List of Documents, Exhibits, and Other Attachments

J	List of attachments

Part IV - Representations and Instructions

K	Representations, certifications, and other statements of offerors or quoters
L	Instructions, conditions, and notices to offerors or quoters
M	Evaluation factors for award

A.2 PRE-PROPOSAL CONFERENCES

The CO and the PO may decide that a pre-proposal conference is in the Government's interest. Whenever possible, notice of such a conference should be included in the RFP. If the decision is made after the RFP is issued, all recipients must be provided adequate notice of the time, date, location, purpose, and scope of the conference, and invited to submit questions in advance for inclusion on the agenda. The pre-proposal conference may be used to:

- Clarify complicated work statements;
- Disseminate background data that offer further insight into the size and complexity of the procurement, as well as the risks of undertaking the project;
- Discuss anticipated difficulties during contract administration, including any exceptional demands on a prospective contractor's capacity and capability;
- Disclose any ambiguities, errors, or omissions in the RFP that may later be corrected in a written amendment; and
- Provide any additional information that is better presented at a conference or that may not have been known at the time the RFP was issued.

The pre-proposal conference is conducted by the CO, with the PO in attendance to provide support. The CO is responsible for determining the agenda and ensuring that a record of conference proceedings is prepared for distribution to all recipients of the RFP, whether or not they attend the conference.

A.3 AMENDING THE SOLICITATION

It may be necessary to amend the RFP during the solicitation period. This circumstance could occur for a variety of reasons -- for example, material changes are made in the specifications, terms, or conditions contained in the original solicitation; or quantities are increased or decreased. Amendments to solicitations increase administrative effort and costs, and they may delay contract award and performance. For this reason, they should be held to a minimum through careful acquisition planning. When an amendment is unavoidable, contracting personnel prepare and distribute it to all recipients of the RFP. Any amendment to an RFP must provide a reasonable time for potential offerors to respond to the change.

B. SOLICITATION PERIOD

B.1 RECEIPT AND MANAGEMENT OF PROPOSALS

Proposals received under a competitive procurement may be accepted only by the CO. Their receipt should be recorded by time and date, and they should be properly safeguarded by the CO until the deadline for submission has passed.

No proposal received after the time and date specified in the RFP may be accepted unless it is received before an award is made and was:

- Sent by registered or certified mail not later than the fifth calendar day before the date specified for receipt of offerors; or

- Sent by mail and it is determined by the CO that late receipt was solely the fault of the Government; or

- The only proposal received.

One of the most important administrative responsibilities of program and contract personnel during the pre-award period is to maintain the confidentiality of the proposals received. Unless offerors are assured that their data will not leak out to their competitors, they may be unwilling to provide the Government with technical data and other essential information about their operations. However, care must be taken when considering the use or disclosure of technical data to ensure that USAMRDC has sufficient rights to use the data in the desired manner. The receipt, storage, and handling of proposals must be treated with all the safeguards necessary to prevent offerors from receiving information that might give them a competitive advantage.

In addition, program personnel must not reveal any information related to the identity of potential contractors, information concerning any proposal, or the status of any proposal in relation to others. Release of such information could jeopardize any resultant award and subject the persons involved to disciplinary action.

After the closing date, the CO will use a transmittal memorandum to forward the technical proposals to the PO or SSEB panel chairperson for evaluation and to establish a date for receipt of the technical evaluation report. The CO will retain the business proposals until the technical evaluation report is completed.

B.2 COMMUNICATION WITH OFFERORS

To ensure that the competition is fair and equitable, every firm must be provided with the same information. Under no circumstances may any Government employee take any action that might give one firm an advantage over another.

In the interval between the time the RFPs are mailed and the contract is awarded, only authorized procurement personnel should have any contact with the offerors. The RFP gives the name of the CO and states that only he/she represents the Government. All correspondence to prospective contractors relating to this acquisition must be signed by the CO or the authorized representative, and all correspondence from prospective contractors relating to this acquisition must be received by the CO.

If, for any reason, one offeror is given information that goes beyond what is contained in the RFP, the same information must be given to all other organizations responding to the solicitation. This must be done by means of a formal amendment that corrects, clarifies, or changes RFP requirements.

C. REVIEW OF PROPOSALS

USAMRDC policy is to select contractors on the basis of a competitive, objective review, and to document source selections thoroughly. This review is performed by a SSEB named by the program office funding the procurement, and convened by the CO.

C.1 SOURCE SELECTION EVALUATION BOARD (SSEB)

The SSEB is responsible for evaluating the original proposals; making recommendations to the chairperson regarding clarifications and deficiencies; reviewing supplemental, revised, and/or "best and final" offers; and, if required, assisting the CO during discussions and negotiations.

To the extent possible, the same evaluators should be available throughout the entire evaluation and selection process to ensure continuity and consistency in the treatment of proposals. However, it is not always necessary for the SSEB to evaluate revised proposals. The chairperson, with the concurrence of the CO, may decide not to have the panel evaluate the revised proposals. This decision must be fully documented by the chairperson and approved by the CO. The following circumstances are examples of instances when the panel need not review revised proposals:

- The answers to the questions do not have a substantial impact on the proposal;
- The "best and final" offers are not materially different from the original proposals; or
- The rankings of the offerors are not affected because the revisions to the proposals are relatively minor.

Attendance by the evaluators is mandatory when the CO considers the SSEB meeting to be necessary. When the chairperson determines that an evaluator's failure to attend the meetings is prejudicial to the evaluation, the chairperson may replace the individual after discussing the situation with the CO and obtaining both CO concurrence and the approval of the program official responsible for recommending the panel members.

Whenever continuity of the evaluation process is not possible, and either new evaluators are selected or a reduced panel is used, each proposal being reviewed at that stage of the acquisition should be reviewed by all members of the revised panel unless this is impractical because of the receipt of an unusually large number of proposals.

The SSEB should be composed of Government employees. Outside evaluators may be used when expertise is required that is not available within the Government, or as required by law.

Business proposals are evaluated after the CO has accepted the technical evaluation. Evaluation of business proposals is conducted only for those proposals that are in the competitive range. Although the panel's primary responsibility is to evaluate technical proposals, it also may be asked to comment on some aspects of the business proposal. Generally, these will be limited to quantitative elements of cost, such as the number of hours of a given skill required to accomplish a task, the amount and destinations for travel, etc. These cost elements will also help the technical evaluation panel judge an offeror's understanding of the requirement.

C.2 ROLE OF THE PROGRAM OFFICER

As the CO's technical advisor for the acquisition, the PO responsibility is to recommend panel members who are knowledgeable about the technical aspects of the acquisition, and who are competent to identify the strengths and weaknesses of the various proposals.

If a panel member has an apparent or real conflict of interest related to a proposal being evaluated, that member must be replaced with another evaluator. If a suitable replacement is not available, the panel must perform the review with one less evaluator. Each SSEB member will be asked to complete a DD Form 1555.

The PO should submit the recommended list of SSEB members to the CO, who reviews the recommendations and appoints the SSEB members.

C.3 READING AND SCORING PROPOSALS

Normally the SSEB convenes to evaluate the proposals, unless the CO decides this is not feasible or practicable.

The CO is responsible for keeping track of all copies of the technical proposals. The CO generally distributes the technical proposals by mail prior to initial panel meeting and establishes procedures for securing the proposals whenever they are not being evaluated. After the evaluation is complete, all proposals must be accounted for by returning them to the CO, who will destroy them, or file them in a way that will maintain their confidential nature.

The CO should provide written guidance to the panel, to include:

o An explanation of conflicts of interest;

- The necessity of rereading and understanding the solicitation, especially the SOW and evaluation criteria, before reading the proposals;
- The need for evaluators to restrict the review only to the solicitation and the contents of the technical proposals;
- The need for each evaluator to review all the proposals;
- The need to watch for ambiguities, inconsistencies, errors, and deficiencies that should be noted;
- An explanation of the evaluation process and what will be expected of the evaluators;
- The need for the evaluators to be aware of the requirement to have complete written documentation of the individual strengths and weaknesses that affect the scoring of the proposals; and
- An instruction directing the evaluators that, until the award is made, information concerning the acquisition must not be disclosed to any person not directly involved in the evaluation process.

Every evaluator should read each proposal, describe strengths and weaknesses, and develop preliminary scores in relation to each evaluation criterion set forth in the solicitation. The evaluators use either the rating sheets in the source evaluation plan (discussed below) or rating sheets approved by the CO when a source evaluation plan is not required.

Each evaluator individually scores each proposal, judging the merits of each against the evaluation criteria published in the RFP. No factors other than those set forth in the RFP may be used.

After individual review, the evaluators should discuss in detail the strengths and weaknesses described by each evaluator. Evaluators may change their numerical scores at this time if they believe they have gained a new understanding of the requirements and the proposed approach, but they should not feel pressured to make changes to conform to the group if they do not wish to do so. The panel collectively ranks the proposals. Generally, this is done by totaling the numerical scores assigned to the criteria by each evaluator, and developing an average rating for each offeror. Other methods are permissible, depending on the rating plan employed. In any case, numerical scores must be accompanied by a supporting narrative that discusses what was considered in the scoring.

When the proposals have been ranked, the evaluators should then identify each as either acceptable or unacceptable. A proposal may be rated as technically unacceptable if it does not meet a design or performance requirement, or if it deviates from the criteria set forth in the RFP. Predetermined cutoff scores cannot be used.

C.4 THE SOURCE SELECTION EVALUATION BOARD REPORT

A Source Evaluation Report must be prepared and signed by the Board Chairman for submission to the CO. The report is maintained as a permanent record in the contract file. The report should reflect the ranking of proposals and identify each proposal as acceptable or unacceptable. The report must also include a narrative evaluation specifying the strengths and weaknesses of each proposal, a copy of the rating sheet and any reservations, qualifications, or areas to be addressed that might affect the selection of sources for negotiation and award.

The report also should include specific points and questions that are to be raised in discussions or negotiations. A determination of technical unacceptability must be supported with concrete technical data. The use of phrases such as "it could not be determined" and "sketchy presentation" is not adequate support for unacceptable ratings. The narrative forms the basis for later debriefings; specific references and terms must be used. Minority reports of individual Board members may be included.

C.5 REVIEW OF BUSINESS/COST PROPOSALS

The CO is responsible for evaluating business considerations, i.e., those factors relating to cost/price analysis and determination of contractor's responsibility (e.g., adequate financial resources, ability to comply with delivery or performance schedule, satisfactory record of performance, etc.). Business evaluations normally center around cost analysis and analysis of contractor's financial strength and management capability.

Each business proposal requires some form of price or cost analysis. The CO must exercise judgment in determining the extent of analysis in each case. The record must be carefully documented to disclose the extent to which the various elements of cost, fixed fee, or profit contained in the contractor's proposal were analyzed. Elements considered in the cost analysis generally include direct material and labor costs, subcontracting costs, overhead rates, general and administrative expenses, travel costs, and profit or fee. Elements considered in evaluating contractor's financial strength and management capability include organization, past performance on similar contractual efforts, reputation for reliability, availability of required facilities and personnel, cost controls, accounting policies and procedures, purchasing procedures, personnel practices (Equal Employment Opportunity, etc.), property accounting and control, and financial resources.

In addition, adequacy of the contractor's facilities and key personnel critical to contract performance should be evaluated.

The PO and/or the SSEB should analyze such items as:

- The number of labor hours proposed for various labor categories;
- The mix of labor hours and categories of labor in relation to the technical requirements of the project;
- The types, numbers, and hours/days of proposed consultants;
- The logic of proposed contracting;
- The proposed travel, including number of trips, locations, purpose, and travelers; and
- The type and quantity of data processing.

The PO and/or the SSEB should tell the CO whether these elements are necessary and reasonable for efficient contract performance. Exceptions to proposed elements should be supported in sufficient detail to allow the CO to negotiate effectively.

In addition, the CO may request that the SSEB review cost or pricing data as a means of facilitating the decision about including a proposal in the competitive range. Situations that may make such a review necessary include:

- A suspected "buy-in" (i.e., a deliberately low bid made with the expectation that the resulting loss will be made up in modifications to the contract or in future contracts);
- Large difference in cost or price among the proposals;
- Proposals receiving a high technical rating that have relatively high costs; and
- Proposals receiving low technical rating that have relatively low costs.

The comparison of cost data with technical factors and information about whether prices are realistic should help the CO decide which proposals to include in the competitive range.

C.6 DETERMINING THE COMPETITIVE RANGE

The FAR requires that written or oral discussion be conducted with all responsible offerors who submit proposals judged to be within the competitive range, considering price and other factors. A proposal must be included in the competitive range unless there is no real possibility that it can be improved to the point where it becomes the **most** acceptable. This provision is designed to save both the Government and potential contractors the time and expense of participating in negotiations, and revising, preparing, submitting, and evaluating final proposals in cases where the offeror's initial proposal is such that there is clearly no possibility of that offeror being selected for contract award.

The CO is responsible for determining the competitive range, although the results of the technical evaluation will weigh heavily in making this determination. All determinations regarding whether to include a proposal in the competitive range must be completely documented, including the salient reasons for the determinations.

Some of the factors that the CO should consider in determining the competitive range are:

- The relative importance of cost, compared to technical factors;
- The possibility of significantly reducing the cost of a proposal with an unreasonably high price without undermining the technical merit, if the offeror otherwise has a reasonable chance to receive an award; and
- The likelihood of reducing the cost or price of a proposal that exceeds the Government's requirements.

The competitive range must be determined on the basis of the array of scores or relative ranking of the offerors, but not on the basis of a predetermined passing score. Borderline proposals must not be excluded from consideration automatically if there is a reasonable chance that clarification or discussion will make them acceptable.

No offeror may be eliminated from the competitive range solely because of an offer to deliver services or supplies of a higher quality than required. If there is no substantial basis for distinguishing between the technical excellence of proposals meeting the Government's requirements, cost or price analysis should then become the controlling factor.

The CO and PO should discuss uncertainties and/or deficiencies that are included in the source evaluation report for each proposal in the competitive range. Technical questions should be developed by the PO and/or the SSEB, and should be included in the source evaluation report. The management and cost or price questions should be prepared by the CO with assistance from the PO and/or board, as required. The CO will then request an audit of cost or price proposals in the competitive range by the Defense Contract Audit Agency.

The method of requesting offerors in the competitive range to submit the additional information will vary depending on the complexity of the questions, the extent of additional information requested, the time needed to analyze the responses, and the schedule for making the award. However, to the extent practicable, all questions and answers should be in writing. Each offeror in the competitive range must be given an equitable period of time to prepare responses to questions, to the extent practicable.

D. NEGOTIATIONS

Developing the Government's negotiating goals is a process that will continue to require close coordination among the CO, the PO, and, in many cases, the evaluation panel. Although the CO is responsible for developing the Government's objectives and the strategy for meeting those objectives, this usually requires the cooperation of the other members of the Government team.

Often the CO will hold a pre-negotiation meeting to discuss negotiation goals and strategy, and to develop a unified negotiating position. In establishing a negotiating strategy, the CO and the PO determine:

- The subjects to be discussed;
- The content and presentation of revised positions;
- Requirements for support of positions; and
- All other tactical procedures for reaching agreement.

D.1 WRITTEN AND ORAL DISCUSSION

Either written or oral negotiations must be conducted with each offeror whose proposal is within the competitive range. In some cases, the CO will represent the Government in negotiating with offerors; in other cases there will be a negotiating team composed of those individuals with skills and backgrounds appropriate for the specific acquisition. In either case, the CO is the focal point and controls the negotiations, with the other members present in an advisory capacity. The CO may elect to have various members of the team lead the negotiations in particular areas. However, the CO should always be in control of the overall negotiations.

Negotiations are carried on separately with each offeror in the competitive range. The goal is to achieve a contract agreement. There should be no reference in discussion with any offeror to the proposal of any other offeror. In fact, no offeror should even be told whether there are any other offerors.

The CO points out to each offeror the ambiguities, uncertainties, and deficiencies, if any, in its proposal. Each offeror is then given a reasonable opportunity to support, clarify, correct, improve, or revise its proposal. No offeror may be given information that will give a competitive advantage over other offerors.

To complete negotiations properly, the CO must advise each offeror within the competitive range that negotiations are being conducted, that the offeror is being asked for its "best and final offer," not merely to confirm or reconfirm prior offers, and that any revision or modification of proposals must be submitted before the negotiation cut-off date.

D.2 BEST AND FINAL OFFERS

A request that offerors submit "best and final" offers allows them to change their proposals to reflect any revision or modification in their proposals that they may wish to make as a result of negotiations. The request also communicates the closing of negotiations.

Typically, best and final offers will result in revised cost proposals, technical proposals, or both. These revised proposals then become the definitive offers, which the Government will use in determining which offeror to select for contract award. All offerors are given a common cut-off time to submit best and final offers. Offerors are prohibited from introducing new concepts or approaches at the best and final offer stage of the solicitation process.

Best and final offers are subject to a final evaluation of price or cost and other salient factors by the CO and PO, with assistance from a cost/price analyst, and an evaluation of technical factors by the SSEB, as necessary. Proposals may be technically rescored and reranked by the SSEB and a new source evaluation report prepared. To the extent practicable, the evaluation should be performed by the same evaluators who received the original proposals.

D.3 THE BUSINESS CLEARANCE MEMORANDUM

The business clearance memorandum or summary of negotiations is a complete record of all actions leading to award of a contract. It is prepared by the CO in sufficient detail to explain and support the rationale, judgments, and authorities upon which all actions were predicated. The memorandum documents the negotiation process and reflects the negotiator's actions, skills, and judgments in concluding a satisfactory agreement for the Government. The PO should assist the CO in providing documentary evidence to support the justification for award.

E. SELECTION AND AWARD

Contract award should be made to "the offeror(s) whose proposal(s) offers the greatest advantage to the Government, price and other factors considered."

As stated earlier, it is usually necessary to conduct a second technical evaluation of proposals submitted as best and final offers. This second evaluation produces a ranking of proposals that aids in the selection of one (or more) offer for contract award.

USAMRDC does not specify a formal source selection procedure. In most cases, the CO makes the source selection based, at least partially, on input from the PO. In some cases, where large and/or potentially sensitive acquisitions are involved, the CO establishes a source selection procedure before initial proposals are received. Such a procedure could take various forms. The most common is having a source selection official established who makes the decision. A procedure for selection of contractual sources for Non-major Medical Defense Systems is included in the Acquisition Instructions issued by the AMO.

The CO is responsible for preparing the final contract document. Before release of this document to the contractor for signature, the CO coordinates with all parties to the negotiation to ensure that the final document fully delineates the agreement reached at negotiations and is representative of the needs of the program office. The CO reviews all the contract and file documents for completeness, accuracy, and compliance with requirements.

The CO then transmits the contract package to the contractor for acceptance and signature. The signed contract is returned to the CO, who signs the contract on behalf of the Government. The contract becomes effective on the date signed by the CO, unless otherwise specified in the contract. Finally, a copy of the fully executed contract is forwarded to the contractor, as well as to the PO, or COR.

F. POST AWARD ACTIVITIES

F.1 PUBLICIZING THE AWARD

All contract awards of more than $100,000 are publicized in the Commerce Business Daily, however, the dollar threshold is not a prohibition against publicizing an award of a smaller amount if to do so would be advantageous to the industry or to the Government. Further, all unsuccessful offerors are sent a "Notice of Award Letter." This letter advises them that their proposals were not accepted and gives the name of the successful contractor, the amount of the contract, and the number of proposals received.

F.2 DEBRIEFING UNSUCCESSFUL OFFERORS

A debriefing is intended to:

- Tell an unsuccessful offeror which areas of his proposal were judged to be weak and deficient, and whether the weaknesses or deficiencies were factors in its not having been selected; and
- Identify the factors that were the basis for selection of the successful contractor. If the ability of the successful offeror to satisfy the mission requirement was the basis for selection, the unsuccessful offeror should be so informed, and given a general comparison of significant areas, but not a point-by-point comparison of all the elements considered in the evaluation criteria. If the successful offeror was selected on the basis of cost, the unsuccessful offeror should be told that was the case. If selection was based on other factors, they should be specified.

If an unsuccessful offeror believes that his failure to obtain the award was not justified, he will rely, at least in part, on the information given in the debriefing to determine whether he should seek recourse. Accordingly, it is essential that a debriefing be conducted in a scrupulously fair, objective, and impartial manner, and that the information given the unsuccessful offeror be absolutely factual and consistent with the findings of the CO and the basis on which the award was made.

A debriefing should not reveal confidential or privileged commercial or financial information, trade secrets, techniques, or processes of the other offerors. Nor, should the debriefing reveal the relative merits or technical standing of the other unsuccessful offerors.

F.3 PROTESTS

Offerors may object to an award by filing a protest with the CO or higher authority. Protests frequently occur when:

- A solicited source is provided with information on the Government's requirements that is not provided to all other solicited sources;
- A program attempts to direct a procurement to a sole source who is only one of a number of sources who might perform the work;
- One source improperly receives information on another's proposal during negotiation; or
- Solicitation requirements are unnecessarily restrictive.

Because protests are often filed based on misunderstandings of the acquisition process or regulations, every debriefing should begin with a detailed description of the process used to select the successful offeror. When a protest is filed, the CO is primarily responsible for resolving it, with assistance from the PO.

SECTION V: CONTRACTING OFFICER'S REPRESENTATIVE

Once the contract is in place, the task of monitoring for contractor, or PI performance begins. Details on the methods and concerns in that monitoring are covered in Section VI, Post-Award Administration. This Section focuses on the Contracting Officer's Representative (COR), the technical or program person who is appointed to help the Contracting Officer (CO) with the monitoring task.

A. COR APPOINTMENT

AFARS states that a CO may select and designate any Government employee, military or civilian, to act as his authorized representative in administering a contract. The CO shall ensure that the COR possesses qualifications and experience commensurate with the authorities with which the COR will be empowered. For this, the CO relies on the recommendation of the laboratory, institute or activity Commander having programmatic responsibility for the contract, with the concurrence of the Commander for whom the COR actually works.

Ordinarily, a COR is designated by a Letter of Appointment from the CO. At a minimum, the Letter of Appointment should contain:

- The names of the COR and the CO
- The contract number
- The specific areas of COR authority and responsibility
- The specific limitations on COR authority
- Detailed description of the files to be maintained
- An emphasis on COR ethics and standards of conduct

The CO is required to furnish copies of the Letter of COR Appointment to the COR and to the Contractor, both of whom must acknowledge receipt of the Letter in writing. Normally, the Letter will make provision for COR and Contractor signatures as endorsements. The CO and COR should ensure that the Principal Investigator (PI) signs with or in behalf of the contractor. The latter step ensures that the PI is aware of the COR and the general role of the COR in the contract.

B. COR RESPONSIBILITIES

The COR has the primary responsibility to see that the technical objectives of the contract are met. Among the activities necessary to meet this responsibility, the COR will:

- Review proposals and preproposals for needed, attainable research objectives. (Prior to formal COR appointment)
- Aid PO in drafting workable, appropriate contract Statements of Work (SOW). (Prior to formal COR appointment)
- Maintain personal contact with the Principal Investigator (PI) to identify technical and administrative problems that can jeopardize contract performance.
- Monitor PI performance to assure compliance with the technical and SOW requirements of the contract.
- Review and, where required by the contract, approve technical reports, drawings, specifications and other technical information to be delivered to the Government under the provisions of the contract.
- Conduct site visits to the PI's laboratory on a regular basis during the term of the contract. The visits must be coordinated with the CO, and AURO or HURRAO, as appropriate Written reports on all such visits are required.
- Maintain a separate correspondence file for each contract.

The COR has the responsibility for guiding and evaluating the performance of the contractor, or PI. In so doing, the COR will ensure that the PI:

- Actually receives a copy of the contract under which the research is to be done.
- Receives fair treatment in light of possible technical and administrative problems that may arise during performance of the contract.
- Is generally aware of the procedures that must be followed to obtain changes, supplements, extensions and other modifications to the contract.
- Understands and meets the deadlines for reports, performance milestones, and contract completion.
- Adheres to contract requirements pertaining to the use of humans, animals and chemical surety materials.
- Maintains an awareness of the part his individual project plays in the overall USAMRDC contract research and development program.
- Receives the guidance and evaluation necessary to ensure a completed, goal-oriented effort.

- Adheres to the SOW in the contract.

In addition, the COR will:

- Advise the CO and PO of delays in meeting milestones, of poor PI performance, and of failures to submit timely, acceptable reports.
- Provide prompt technical review and recommendations regarding all requests for contract changes.
- Assure that changes under a contract are not implemented before written authorization (contract modification) is issued by the CO.
- Review and comment upon inventions discovered under the contract, and follow-up on licensing to the Government.
- Recommend to the CO the disposition of equipment no longer necessary for performance under the contract.

C. COR CONTRACT FILES

COR are expected to maintain a separate file for each contract they oversee. At a minimum, the COR contract file shall contain a copy of:

- Any RFP relating to the contract.
- The proposal on which the contract is based.
- The contract and any amendments.
- Correspondence with the contractor, or PI.
- Correspondence with the CO.
- Correspondence with program officers.
- All reports submitted by the contractor.
- All Memoranda for Record pertaining to the project.
- Reports of inspections and site visits.
- The COR Letter of Appointment signed by CO.

D. COR CAUTIONS

The CO is the Government's authorized agent in dealing with contractors and is the only person who has the authority to negotiate, award, change or amend a contract. This fact leads to several important cautions for the COR:

- Do not act in such a manner as to cause the contractor or PI to believe that the COR has the authority to obligate the Government.
- Do not request or direct the PI to do anything that is not expressed as a term, consideration or provision of the written contract.
- Be certain that the PI does not take suggestions or comments as directions to proceed on a course of action not covered by the contract.
- In recommending requests for changes in a contract, be sure that the change does not add new work, objectives or data for which a new contract might be needed.
- Remember that a COR can be held responsible if a contract goes into time and/or money overrun conditions because of gross negligence in monitoring the technical progress of the contract.

E. COR COMMUNICATIONS

In drafting correspondence to the contractor and in oral communication, the COR must exercise care not to accidently generate the basis for claims or delays. When communicating with contractor personnel, or when conveying technical or assessment information, it is critical that the COR not instruct, supervise, or attempt to control contractor efforts except as specifically authorized in the contract SOW.

No one disputes that reasonably open and honest communication between the COR and the contractor can enhance performance. Professional discussion of options and alternative approaches are necessary. The COR must remember, however, that there is a contract which defines rights and obligations of the parties. All communications with the contractor must be viewed in this light. The contractor has a right to proceed in any manner which is consistent with the terms of the contract. Excessive involvement of the COR in the day-to-day conduct of the project or comments on performance that are too strongly or improperly worded can interfere with the contractor's rights under the contract. Even the appearance of unauthorized direction to the contractor when none was intended can lead to contract claims or other problems.

Consequently, the COR must be discrete. He should think twice and seek the advice of the CO if there is any question about the effect of any statement on the contractor's obligation to perform.

All communications of any significance shall either be in writing, or confirmed in writing as soon as possible. The COR will provide information copies of such correspondence to the CO and appropriate AMLO. It follows that the CO shall provide copies of all his significant, technically-related correspondence and reports to the COR.

F. MISCONDUCT IN SCIENCE

"Misconduct" has been defined by the National Science Foundation (NSF) and the National Institutes of Health (NIH) to mean (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research; (2) material failure to comply with Federal requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other legal requirements governing research.

In recent years the issue of misconduct in science has become a matter of concern to research institutions, individual scientists, sponsors of research, and the general public. Although instances of verified misconduct are rare, virtually every instance raises serious questions about the integrity of research and, since most biomedical and behavioral research is Federally funded, about the stewardship of Federal funds.

NIH and NSF have taken the position that, while the incidence of misconduct is low, a standard procedure for handling allegations of misconduct is in the best interests of all concerned. Accordingly, they have issued separate, but nearly identical policy statements on misconduct. The one for the NSF is found under 45 Code of Federal Regulations - Part 689.

In essence, the NSF and NIH policies define misconduct, indicate the types of penalties that may be applied (they range from a letter of reprimand, through contract termination, to prosecution by the Justice Department), and describe an investigational procedure which leaves much of the determination of guilt or innocence with the research institution. The Agencies follow the probe and step in when there are delays or problems.

USAMRDC policy parallels the NSF/NIH lead. Instances of alleged misconduct shall be reported to the PARC. In turn, the PARC will appoint a Misconduct Policy Officer (MPO) who will coordinate appropriate USAMRDC participation in the matter. Communication with MPO counterparts at NSF and NIH is encouraged. Final disposition of each case is left to the Commanding General, USAMRDC.

SECTION VI. POST-AWARD ADMINISTRATION

Contract administration involves ensuring that the contract is performed-- as written--by both the contractor and the Government. No matter what type of contract is involved, a breakdown in administration can undo all previous achievements in placing the contract. The COR must monitor a contractor's progress closely and make known to the CO potential problems that threaten performance so that remedial measures may be taken. The critical need for effective contract administration is underscored by the realization that the typical principal investigator may never see, much less read the contract under which he conducts the contracted effort.

A. CONTRACT ADMINISTRATION

Administration of a contract begins after negotiations have been successfully concluded and the contract has been signed; it ends at the closeout of the contract when performance has been completed and the contractor has received his final payment. Therefore, contract administration includes all the functions and duties relating to such tasks as:

- Monitoring the contractor's technical progress;
- Controlling government property;
- Monitoring subcontractors;
- Reviewing contract modifications and terminations;
- Performing other administrative tasks required by the contract.

Contract administration can be simple, or complex and time consuming, depending on the type of contract, contractor performance, and the nature of the work. For example, a fixed-price contract requires relatively little post-award administration, whereas a cost-type contract requires careful technical surveillance and auditing of costs; it also imposes an administrative burden on both the Government and the contractor. No matter what type of contract is involved, however, it should be closely monitored. If technical or business problems are not solved before they disrupt the contractor's scheduled performance, the Government may find itself in a situation with either a pending termination or a forced contract modification. Either is a poor remedy, considering the lost time or unnecessary costs that could have been avoided if the Government had administered the contract properly.

A.1 LIMITATIONS ON THE COR

Contract administration is the responsibility of the CO. The CO is the only person who may modify the contract, or take any action to enter or change a contractual commitment on behalf of the Government. The legal responsibility for the contract rests with the CO, who delegates certain authority to the COR and holds the COR accountable for exercising that authority properly.

In most cases, the CO authorizes the COR to perform the following functions independently in administering the technical aspects of the contract:

- Correspond directly with the contractor;
- Conduct technical conferences with the contractor;
- Conduct on-site visits in coordination with the CO;
- Conduct animal care and use inspections on behalf of the AURO;
- Ascertain compliance with Federal regulatory requirements;
- Evaluate all reports and technical data submitted by the contractor.
- Provide necessary interpretation for the contractor on technical matters that are:

  --within the scope of the contract as written, or

  --will not affect cost, period of performance, or other terms and conditions of the contract.

A copy of all correspondence, trip reports, data and PI report evaluations, conference summaries, and records of pertinent telephone conversations with the PI must be sent to the CO.

If there is any question as to the effect of these functions on contractor performance or contract provisions, the COR is cautioned to check with his AMLO or the CO, first.

In addition to exercising delegated authorities, the COR is expected to:

- Maintain a file documenting significant actions and containing copies of trip reports, correspondence, and reports and deliverables received under the contract; and

- Advise and assist the CO, as necessary, in administering the business aspects of the contract, reviewing requests, reports, and deliverables; coordinating program office decisions as they bear on the contract; review and comment on invention disclosures; and preparing final summary statements for contract closeout, including recommendations for disposition of equipment.

The COR is not authorized to issue or approve changes in the contract or to enter into any agreement, contract modification, or any other matter changing the cost or terms and conditions of the contract. The COR and the contractor are both informed in writing of this fact by the CO letter of COR appointment. However, in the course of seemingly routine technical discussions, it is not unusual for contractors to act on many COR recommendations without regard to contract provisions or limitations. It is for this reason that cooperation between the COR and CO is essential.

On the other hand, should a contractor feel that COR directions are outside the scope of the contract, the contractor is directed by contract provisions not to proceed. Instead, he must notify the CO within five working days, specifying the nature of the objection. After consulting with the COR, the CO may:

- Issue a contract change;
- Rule that the COR direction is within the scope of the contract; or
- Direct the contractor to ignore any, or all of the technical directions causing the complaint.

A.2 PLANNING FOR ADMINISTRATION

Planning the administration of a contract at the outset of the project is a necessary step in effective contract administration. This planning is needed to assure that the administrative steps intended are consistent with the specific procurement. Also, the analysis of contract administration requirements can disclose potential problems in performance of the work that might have been overlooked prior to contract award, making it possible to take early corrective action before they become serious obstacles.

The planning should be based on a review and analysis of the project and contract requirements, and include such things as an analysis of the need for and timing of such things as performance and cost reviews, inspections, scheduled delivery of Government-supplied items, subcontracts, key personnel issues, monitoring of the contractor's compliance with terms and conditions, and other administrative duties. Depending on the nature of the contract work, it may be helpful to discuss the planning with the contractor to arrive at a common understanding of what will be expected.

A post-award conference may be scheduled by the CO to assure that all parties to the contract are aware of requirements, responsibilities and procedures.

At a minimum, effective contract administration requires the COR to:

- Read and understand the contract, and ensure that the contractor does the same.
- Develop a post-award milestone chart in coordination with the CO and contractor.
- Read and act promptly on progress reports.
- Review progress and problems with the CO regularly.
- Visit the contractor site periodically. Give the CO advance notice of such visits.
- Stay on top of his responsibilities in the contract.

A.3 CONTRACT REVIEW

Once a contract has been awarded, the COR will receive a copy of the contract. The COR's first responsibility is to read and understand the contract, keeping in mind the basic rules of contract interpretation.

Government contracts are subject to essentially the same common law rules of interpretation applied to other contracts. Several of these basic rules are:

- The intent of the parties must be gathered from the whole contract, not from individual clauses or phrases.
- The dominant purpose of and the interpretation adopted by the parties will be used to ascertain the meaning of the contract provisions.
- Specific provisions prevail over general provisions when they are in apparent conflict.
- A standard clause entitled "Order of Precedence" resolves inconsistencies within the contract provisions by assigning precedence in a specified order within the contract parts.
- An ambiguous provision susceptible to more than one interpretation will be interpreted against the party responsible for creating it. In Government contracts this is almost always the Government, as the contract provisions are normally prepared by the Government.

Equally important to the performance of Government contracts, or more aptly the risk thereof, are the specifications or SOW that the contractor must meet. Contract specifications dictate the nature and degree of performance to be undertaken by a contractor. When the specifications are accurate, complete, and realistic the only issue is contractor performance.

On the other hand, where specifications are shown to be defective or are such that performance is impossible, the contractor may either be excused for lack of performance or may be entitled to additional compensation if the cost of performance is increased.

Similarly, a mutual mistake of fact may result in an adjustment to the contract price. In this situation, there must be a mistaken concept by both parties as to a material fact that results in performance being more costly. The contractor, to recover the extra cost of performance, must show that the contract did not allocate the risk of such a mistake and that the Government received a benefit from the extra work for which it would have been willing to contract had the true facts been known.

The COR might use the contract format outline shown in Section IV as a guide for a complete review of a contract.
The items shown below are among those of obvious and immediate interest.

Cover Page:

- Contract Number
- Effective Date - Official start date of the contract.
- Contractor - Note that the contractor is a laboratory, commercial firm, or university, not the principal investigator.
- Project Title
- Term of the Contract
- Funding to Date
- Total Amount of Contract Funding

Description/Specifications (Section C):

- Contains the SOW. Any significant deviations from the COR understanding should be reported immediately to the CO.
- Note that the PI name finally appears in the contract near the end of this section.

Deliveries or Performance (Section F):

- This section will describe the reports and other deliverables that are expected of the contractor, or PI.
- The COR should use the "effective date" of the contract to prepare a chart that shows when the various reports for the contract are due.

Contract Administration Data (Section G):

- This section outlines the dates on which incremental funds will be released for contractor use.
- Bear in mind that there is nothing automatic about the release of incremental funding. The funds will be released by the CO only after COR recommendation.

Special Contract Requirements (Section H):

- This section contains the special requirements for human, animal and surety material use in the contract effort.

A.4 POST-AWARD ORIENTATION AND CONFERENCES

The fundamental task of Government contract administrators is to ensure that the contractor fulfills its obligations. Post-award orientation is a useful tool for getting good contractor performance by:

- Ensuring that the contractor understands the contract requirements;
- Clarifying contract administration procedures that will be applied;
- Clarifying the roles of Government personnel who will be involved in administering the contract.

In relatively simple acquisitions, post-award orientation may be accomplished in a letter. This letter should identify the Government officials responsible for contract administration and clearly identify any special or unusual requirements, such as production tests, special reports, and subcontracting consent requirements.

Any formal post-award orientation conference should be preceded by a meeting of all the Government personnel with administrative responsibilities for the contract to establish a coordinated Government position regarding the agenda and the specific responsibility of each Government representative. The agenda should cover all matters that need to be clarified or otherwise discussed with the contractor to avoid misunderstanding of the contract requirements. These matters might include:

- Clarification of the Statement of Work;
- Clarification of the specifications;
- Authority of USAMRDC personnel;
- Contract reporting and delivery requirements;
- Approval requirements; e.g. foreign travel.
- Use of Government facilities;
- Furnishing and control of Government property;
- Special contract provisions; e.g. animal/human use.
- Quality control and testing requirements;
- Procedures for monitoring and measuring progress;
- Billing, voucher approval, and payment procedures.
- Progress target dates;
- Subcontract procedures;
- Anticipated problem areas;
- Allowability of cost determinations.

If the CO does not chair the orientation conference, this responsibility can be delegated to the COR. The conference should be conducted in a businesslike manner, with the recognition that both parties have an existing contractual relationship and that the purpose of the conference is to promote accurate understanding of the contract, not to alter it.

Post-award orientation of subcontractors is the responsibility of the prime contractor. If it appears desirable for Government personnel to attend a subcontractor orientation conference, any Government representative attending should recognize that the Government has no rights of contract with the subcontractor. Therefore, all instructions, interpretations, or other contractual dealings with the subcontractor are the business of the prime contractor, not the business of the Government.

A.5 PRIOR AUTHORIZATION FOR EXPENDITURES

In order to control the contractor's cost expenditures and to further ensure that USAMRDC objectives are met, contract provisions are often used that require the contractor to obtain prior authorization from the CO before he may take specific actions or incur certain costs. For example, prior consent is required for subcontracting; prior approval is needed for reimbursement of costs to be incurred in excess of limitations set in cost reimbursement contracts; and, in USAMRDC, prior approval is needed before a contractor may purchase equipment valued above $5000, even though the items are in the agreed-upon budget. In all cases, the CO is responsible for providing the approvals. However, since the underlying circumstances that call for approval may directly relate to the technical performance of the work, the COR will normally be consulted before approval is granted or withheld.

A.6 COST AND SCHEDULE PERFORMANCE DATA

Contracts for materiel acquisition will contain requirements for cost and schedule performance data, as specified by the appropriate Project Management Office in the US Army Medical Material Acquisition Agency (USAMMDA).

A.7 GOVERNMENT PROPERTY

Government regulations state that a contractor may be provided Government property or allowed to acquire such property at Government expense upon determination that:

- No practicable or economical alternative exists; e.g., acquisition from other sources, utilization of subcontractors, rental property, or modification of program project requirements, etc.;

- The Government receives adequate consideration for providing the property; or

- Furnishing Government property is likely to result in substantially lower cost to the Government for the items produced or services rendered when all costs involved are compared with the cost to the Government of the contractor's use of privately-owned property.

The determination that it is necessary to provide a contractor or subcontractor with property will be made by the CO with the advice of the PO and an agency property official.

The CO prime responsibility in administering Government property furnished to a contractor or acquired by the contractor as a direct cost item under a cost reimbursement contract, is to ensure that the contractor complies with the provisions of the Government-furnished property clause to the contract, and performs the necessary surveillance of various aspects of maintenance, use and disposition. In addition, the CO renders decisions regarding liability, whether Government or contractor, for loss, damage or destruction of Government property.

When Government property is provided under a contract, the COR frequently will be asked to advise or assist the CO in administering its use.

A.8 KEY PERSONNEL CLAUSE

As noted in an earlier section of this guide, research contracts will generally include a "Key Personnel" clause which specifies the key contractor research staff members for the project by name. The purpose here, obviously, is to ensure that the minds and talent which prompted USAMRDC to award the contract are those which will execute the proposed plan.

During contract performance, the COR should determine whether key personnel are actually performing the functions for which they were promised in the proposal. In smaller projects, this is easily accomplished since the few key persons named will tend to be the ones with whom the COR has contact. On larger projects, this may not be the case, and the COR must make specific checks on the participation of the named key people.

When a contractor proposes a substitution of key personnel, the CO will forward the justification to the COR for review. The COR should review the contractor's original proposal to check on the qualifications of the personnel being replaced. If the proposed substitute does not have appropriate credentials, the COR should so advise the CO. The CO may then refuse consent and require the contractor to propose another substitute. Not all substitutions are a matter of the contractor's choice. People retire, resign or die. Some latitude is clearly indicated in those circumstances. However, if the substitution is within the control of the contractor, it is good practice to be very strict in application of the "Key Personnel" clause. If application is loose, USAMRDC could become the victim of "bait and switch" tactics.

The COR must never insist on a specific individual as a replacement for a key person. This is a contractually unwarranted invasion of the contractor's management prerogatives. USAMRDC has a right to demand an equally qualified person. The contractor must meet this obligation, but the manner is up to him.

B. SUBCONTRACTS

Subcontracting is contracting between a prime contractor and one or more other organizations or individuals to obtain goods or services to carry out the objectives of the prime contract. In the case of a prime contract, the Government is the buyer and the contractor is the seller. However, when the contractor lets subcontracts, the contractor becomes the buyer, while the subcontractor becomes the seller. The prime contractor and the Government have a direct legal relationship. No such direct legal relationship exists between the Government and the subcontractor. Even in acquisitions where the contract specifies that the Government has a right to review and approve subcontracts, no direct relationship between the Government and the subcontractor is established.

B.1 ADMINISTRATION OF SUBCONTRACTS

The prime contractor, not the Government, is responsible for administering subcontracts. When the Government buys the services of a contractor it is buying, among other services, its management services. It is the responsibility of the prime contractor in an acquisition to ensure the performance of the subcontractor. Nevertheless, there are a number of monitoring and contract administration functions a COR can perform to promote effective subcontract operations.

B.2 ACTION PRIOR TO AWARD

As may be appropriate to his knowledge or background, the COR can help the CO with the subcontracting process by reviewing the proposed subcontract in light of the following questions:

- Is the decision to subcontract consistent with the contractor's approved make-or-buy program, if any?
- Is the subcontract for special test equipment or facilities that are available from government sources?
- Is the selection of the particular supplies, equipment, or services technically justified?
- Has the contractor complied with the prime contract requirements regarding labor surplus areas or small business subcontracting, including, if applicable, its plan for subcontracting with small business concerns and small disadvantaged business concerns?
- Was adequate price competition obtained or its absence properly justified?
- Does the contractor have a sound basis for determining the responsibility of the particular subcontractor?
- Has the contractor performed adequate cost or price analysis or price comparisons and obtained accurate, complete, and current cost or pricing data, including any required certifications?
- Has adequate consideration been obtained for any proposed subcontract that will involve the use of Government-furnished facilities?

- Has the contractor adequately and reasonably translated prime contract technical requirements into subcontract requirements?

In reviewing the proposed subcontract, the COR should be especially careful if:

- The prime contractor has had previous subcontracting problems;
- There has been little or no competition for the goods or services;
- There is a close relationship between the prime contractor and the proposed subcontractor; and
- The subcontract is to be placed on a cost-reimbursement, time and material, labor hour, fixed-price incentive, or fixed-price redeterminable basis.

B.3 ACTION AFTER SUBCONTRACT AWARD

After the subcontract has been let, it is the prime contractor's responsibility to manage it. But here again, the COR has certain responsibilities to ensure that the prime contractor is managing it adequately. The COR can review the effectiveness of the contractor's subcontract administration function. Observations can be made of such things as the support, direction, and timeliness of actions provided by the contractor to subcontractors.

An important area to be covered in any review of subcontract administration is the contractor's system for making subcontract changes. Procedures must provide not only for timely processing of changes but also for prompt notification of all parties concerned, including the Government.

Often subcontracting administration is reviewed as part of an overall Contractor Purchasing Systems Review (CPSR). Generally, a review is made of the purchasing system, including its policies, procedures, and performance under that system. The FAR requires that in a CPSR special attention be given to:

- The degree of pricing competition obtained;
- Pricing policies and techniques, including methods of obtaining accurate, complete, and current cost and pricing data and certification as required;
- Whether the contractor has obtained CO consent prior to placing subcontracts falling in the approval zone; and

- Whether the contractor has obtained adequate competition for subcontracts, including competition from small and small disadvantaged firms.

In the review of proposed subcontracts, a major consideration should be the effect of the subcontract on the quality of the services or items to be provided. If the proposed subcontract is considered to be satisfactory in all essential respects, written consent is given by the CO for its award. However, consent does not mean that all the subcontract costs are allowable under a cost reimburseable prime contract, nor is it a determination of the acceptability of the subcontract price in future price negotiations. These are separate questions.

If the proposed subcontract is not acceptable to USAMRDC, it will not be approved. The prime contractor is so notified and told why the proposed subcontract is unacceptable. Other arrangements must then be made for obtaining the proposed work. This may involve altering some of the terms of the subcontract, or it may require selection of another subcontract source. This will depend, of course on the particular reasons for denying consent to the proposed subcontractor.

C. CONTRACT MONITORING

The contractor has primary responsibility for performance of the contract, but the COR and the CO have a vested interest in continually monitoring contractor performance, because unsatisfactory performance under a contract may jeopardize a project or an entire program.

Contract monitoring varies considerably both in intensity and in methodology, depending on the importance and size of the contract effort, as well as on the type of contract. For example, cost-reimbursement-type contracts generally warrant closer monitoring because the Government's risk is higher than under a fixed-price contract.

In monitoring a contractor's performance, the Government is primarily interested in progress toward completion of the specified requirements and the financial status of the contract.

One valuable monitoring tool is the reporting requirements. The Government, in the contract document itself, may require the contractor to provide just about any type of report conceivable. It must be remembered, however, that the Government is paying for any reports required of a contractor as part of the contract price. Reports are discussed in greater detail below.

Additional information may also be obtained in the form of letters and phone calls between the contractor and the COR or CO. Visits to the contractor's facilities are sometimes necessary to evaluate the contractor's performance. However, it is important to maintain a reasonable balance. Although the Government has a right and a duty to monitor contractor performance, Government personnel may be subject to charges of interference in the contractor's operation or of making unreasonable demands if discretion is not used in this area.

C.1 THE NEED TO MONITOR

One of the first things the COR must do in monitoring technical progress and costs is to lay aside any assumptions that the contractor will diligently and faithfully perform precisely what the contract requires. Consider these points:

- The people who propose and negotiate the SOW may not be the same people who are assigned to work on the project.
- Helpers generally have no background in the proposal and subsequent negotiations.
- Since even key people change jobs, it should never be assumed that all contractor personnel have appropriate knowledge of contract methods and goals.
- Even when contractor personnel are fully aware of the contract requirements, they may often be tempted to provide "something else that is just as good" for a variety of seemingly valid reasons.
- Things simply "fall through the cracks."
- The contractor may miss or overlook ancillary, but important, contract requirements like the frequency, content and format of progress reports.

C.2 PROGRESS REPORTS

Progress reports should show whether the contractor is completing milestones on schedule, whether he is applying resources at the level at which he expected to apply them, and whether the quality of the products is at a level consistent with the documented requirements of the contract. This information should be adequate for Government decisions, yet not so extensive, comprehensive and formatted as to create an unnecessary or excessive administrative and financial burden on the contractor. Moreover, the information requirements should obviously not detract excessively from time the contractor might better devote to his technical performance.

In addition to keeping the COR informed of status, the progress report gives the contractor an opportunity to stop periodically and evaluate his efforts in terms of the intent and specifications of the contract. The necessity for writing and analyzing progress reports forces both the contractor and the COR to periodically evaluate the work in relation to all contractual requirements.

Reporting Requirements

The requirements for report frequency, format and content should be stated in the contract so that there is no question regarding their importance to USAMRDC. While several standard enclosures for contracts have been written for this purpose, their use is not mandatory. Program planners may specify virtually any reporting requirements that are necessary. One should bear in mind, however, that all reports are a cost to USAMRDC. Basic requirements now used in USAMRDC contracts are given in Appendix L. The type of information and the amount of detail required in progress reports must be such that:

- The COR will be in a position to detect technical administrative problems associated with the contract in a timely fashion.
- The COR can knowledgeably recommend changes in the work scope or redirect work within the general scope of the contract.
- A record of the contractor's past performance can be developed that will facilitate decisions regarding new or continued support.
- In the extreme, the COR can recommend termination of the contract where progress is unsatisfactory.

The specific information needed to satisfy these conditions will vary somewhat between projects. In general, however, useful progress reports are found to center on the:

- Aims and objectives of the research;
- Scientific and administrative problems;
- Both positive and negative results;
- Analyses and conclusions regarding the research to date;
- Recommendations prompted by the results to date;
- Plans for the next reporting period;
- Administrative status of the project.

Preliminary Data

Contractors should be encouraged to furnish preliminary technical information in their progress reports even though it is tentative and not ready for widespread distribution. Researchers are often reluctant to commit themselves to premature technical data or conclusions, and it may be necessary to assure the contractor that USAMRDC will treat his technical progress information as privileged communications.

COR Responsibility

The COR is responsible for ensuring that a report delivered by the contractor conforms to the technical requirements of the contract. An acceptable progress report will:

- Be submitted according to schedule.
- Present data and results which are commensurate with the maturity of the contract.
- Demonstrate that the contractor is addressing the SOW.
- Include appropriate coverage of technical and administrative problems.
- Outline plans and recommendations which stem from the project findings to date.
- Be written in a format and style which is understandable to a general readership having some background in the topic area under study.
- Contain all pages, figures, tables and supplements that were intended for inclusion by the authors.

The COR progress report review must be conducted promptly out of courtesy for the contractor and to ensure a rapid USAMRDC response in the event of program or contract problems. Where appropriate, the COR should solicit the comments and concurrence of other technical experts and/or from other affected program officers. The acceptance or any required revisions should be transmitted to the contractor without delay.

In the event a report is found to be unsatisfactory, the COR and the CO must determine what further actions are required, seeking the advice of legal counsel if necessary.

In discharging this responsibility, the COR should keep in mind that, once a contractor's report has been formally accepted, the contractor is excused from further performance or correction on that report.

C.3 SITE VISITS

Site visits may be unnecessary for small, straightforward contracts, but when a contract is large and complex, they are indispensable.

Strictly speaking, site visits should be conducted jointly by the COR and the CO, but as a practical matter they are often conducted only by the COR. Irrespective, site visits should be coordinated with the CO, whether or not a representative from that office is making the site visit.

A site visit is usually arranged in advance with the contractor. In rare cases, there may be a reason to make an unannounced visit, but these situations require careful consideration and should have the explicit approval of the CO.

Purpose

There are many reasons for making site visits. These include efforts to:

- Establish or maintain technical credibility with the contractor through face-to-face discussions with the researchers.
- Check actual contract performance against scheduled or reported performance.
- See if the facilities and working conditions are adequate.
- Verify that the number of employees charged to a cost-reimbursement contract are actually performing work under the contract.
- See and discuss project problems at first hand.
- Verify general compliance with AURO and HURRAO requirements.

Checklist

It is highly recommended that the COR conduct his site visit using a checklist. This not only ensures complete coverage of topics and inspections, but aids in the preparation of the subsequent trip report. A sample site visit checklist is shown in Appendix J.

Trip Reports

A written report is required for each site visit. The report should include:

- Reference to the date, place and contract.
- Names of contractor and USAMRDC principals in the visit.
- A summary of the discussions.
- Some comment on the site and contract status.
- Detailed comments on observed discrepancies, particulary those relating to AURO, HURRAO and surety material requirements.

At a minimum, copies of the report are to be sent to the CO and, as appropriate, to HURRAO, AURO or the Safety/Surety office.

D. CONTRACT MODIFICATIONS

A contract modification is a written alteration of such contract provisions as the work statement, period of performance, quantity, price or other provisions of a contract. During the contract life, different types of modifications may be necessary to incorporate new requirements or to handle problems that develop after contract award. Contract modifications must be made in writing by the CO in order to preclude misunderstanding between the parties concerning the work to be performed.

Various contract terms and provisions provide for modifications to a contract if certain conditions arise or if information not known at the time of contract award becomes available. For example, the Government Furnished Property clause provides for equitable adjustment of the contract estimated cost and performance dates in the event the property furnished by the Government is not suitable for the intended use. For another, the Limitation of Cost clause used in cost-reimbursement contracts permits funding of cost overruns, when authorized. These two clauses, and the standard Changes clause, discussed in detail later in this section, are the most commonly used to effect contract modifications.

A supplemental agreement is a bilateral (requested by either the contractor or the government, and agreed to by the other) revision of the contract that either adds work or revises the existing terms of the contract. Such agreements may have cost implications. Supplemental agreements are used, for example, when it is necessary to change the contract price, delivery schedule, quantity, or other terms of the contract; or when the Government wishes to modify a contract and the proposed modification is for work that is an inseparable part of the original procurement.

D.1 CONSIDERATION FOR CONTRACT MODIFICATION

Generally there must be consideration whenever a contract is modified. "Consideration" is the benefit each party confers upon the other for the modification. Contract modifications usually result in price or cost changes. The requirement for consideration, as set forth in various decisions of the Comptroller General, is that no officer or employee of the Government may alter a contract to the prejudice of the Government unless the Government receives corresponding, tangible contractual benefits. Thus, there is no such thing as a "no cost" extension to the period of performance of a contract. If the Government allows a longer period of time for delivery, the "cost" to the Government is its right to delivery of the product or service by the date agreed upon. The law requires the contractor to provide some form of consideration for the Government's giving up of that right. While this is not rigidly enforced in the case of research contracts, the concept remains as a potentially useful management tool.

Certain administrative changes may be made without consideration provided the contractor's rights are not affected; e.g., change in the appropriation data or a change in the paying office, etc. Once a valid contract is executed, no adjustment can be made to its terms merely because it may appear, in retrospect, that either the contractor or the Government has made a "bad bargain."

D.2 MODIFICATION VERSUS NEW ACQUISITION

Before initiating a modification, it is necessary to determine that the change is within the scope of the existing contract rather than a new acquisition outside the scope of the contract. A change in the essential character of services provided under an existing contract, or the addition of work outside the existing scope of the contract, is considered a new acquisition and may not be supported by modification to an existing contract. The general rule may be stated that an existing contract may not be expanded so as to include additional work of any considerable magnitude, unless it clearly appears that the additional work was not contemplated at the time of the original contracting and is such an inseparable part of the work originally contracted for as to render it reasonably impossible of performance by other than the original contractor. The apparent probability that the additional work may be done more conveniently or even at less expense by the original contractor is not controlling as to whether competition is required.

If a new acquisition is indicated, it must be subject to competition prior to award. If the new acquisition is to be awarded noncompetitively, it must be justified as a "less than full and open competition".

D.3 CHANGE ORDERS

The contract clause entitled "Changes" distinguishes Government contracts from other contracts by the control over performance vested in one of the contracting parties -- the Government.

Unlike contracts in the private sector where performance must conform to pre-agreed terms in the absence of a modification issued by both parties, the "Changes" clause in a Government contract allows the Government to alter the work to be performed without the consent of the contractor.

The "Changes" clause provides, in essence, that the CO may, by written order, make any change in the work within the general scope of the contract. Such changes may result also in an appropriate upward or downward equitable adjustment in the contract price, delivery schedule, or time for performance. Additionally, the clause provides that a dispute over the equitable adjustment is a question of fact under the "Disputes" clause, and that nothing in the clause excuses the contractor from proceeding with the contract as changed. This power, unique to Government procurement, allows the CO to alter performance without unnecessary interruption and to subsequently determine the appropriate contract price adjustment.

The "Changes" clause imposes certain requirements for issuing a valid change order. The first of these requirements is that the change be ordered by the CO. The clause also states that the change must be made by written order. One of the more important requirements is that the change ordered must come within the general scope of the contract.

Though these specific requirements are included in the "Changes" clause and are thus a part of the contract, courts and various appeals boards have acted in such a way so as to negate or modify some of the requirements. This is especially true in the area of constructive changes, a particularly important contract monitoring concern for the COR.

D.4 CONSTRUCTIVE CHANGES

A "constructive change" arises whenever, by informal action or inaction of the Government, the situation of the contractor is so altered as to have the same effect as though an order had been issued under the Changes clause. The term "constructive" is derived from the verb "to construe" -- not from "to construct." Thus, the constructive change is a situation that can be construed as having the effect of a Change Order.

There are several ways in which a constructive change occurs. The list provided below is not all-inclusive, nor is it as black and white as it may seem. This is an area of equity or fairness -- and fairness depends greatly on the situation. An action by the

Government may lead to a successful claim by a contractor under such principles, but in a very similar situation, the claim will be successfully defended by the Government.

Common Causes of Constructive Changes

The following are the most common among the many ways in which a constructive change can occur:

- Inadequate (latently defective) specifications;
- Improperly interpreted specifications;
- Overly strict inspection;
- Failure to recognize delays caused by the Government;
- Technical defects in the Change Order process; or
- Improper technical direction.

If a specification is defective in such a way that reasonable review prior to preparation of a bid or proposal would not disclose the defect (i.e., the defect is latent), this has the effect of making the work more difficult for the contractor than is reasonably expected. Adding a work requirement in this accidental manner is tantamount to making a change to the specifications. It leads to an obligation on the part of the Government to make an equitable adjustment in a fashion similar to that which would be made under the Changes clause. This general area includes cases where performance is completely impossible.

If, during the course of contract performance, questions arise concerning the meaning of the specifications or other terms of the contract, the contractor is generally required to inquire of the Government as to the meaning. The Government's interpretation may differ from the contractor's. Under the Disputes clause, the contractor must comply with any "final decision" of the CO. Later, this disagreement may be subject to review by a Claims Court. If it is determined that the Government had required more than a reasonable reading of the specifications would require, then the contractor is entitled to an adjustment.

Overly strict inspection is closely related to erroneous interpretation of specifications. Assume, for example, that a delivery has been made. The COR, in the role of inspector, rejects the items and requires certain corrections. The contractor then makes those corrections. If the contractor later makes a claim for additional work, and it is determined that the initial delivery was not defective, the adjustment will be under the principles of constructive change.

If the Government causes a delay for the contractor, but then insists on having the original delivery schedule met, this is a constructive acceleration. Time should have been added for performance.

Finally, there are the cases of improper technical direction, usually from the COR. The difference between improper technical direction and overly strict inspection or erroneous interpretation of specifications, is that the error occurs because the COR either does not bother to determine the limits of his authority, or deliberately ignores such limits. For example, the COR decides that something needs to be done and attempts to get the contractor to do it for "free." In a great many cases, this kind of error in procedure does not lead to a claim. Contractors will often comply with improper orders for "free" services because they want to maintain the goodwill of the COR, whose opinions can affect their chances for future work. But if this happens too often, most contractors will eventually begin to follow the lead set by the COR. The most common form of this is for the contractor to say to the COR: "We have made several changes for you at no charge; surely, you can overlook this little defect?" Thus contracts with supposedly enforceable obligations on both parties end up becoming a mockery.

Contractors sometimes suggest modifications to the contract work. Like as not, the change will technically improve the contract services or deliverables, and the COR may heartily approve the idea. The COR must beware, however, of leading the contractor to believe that USAMRDC is authorizing the contractor to proceed. It is difficult if not impossible for USAMRDC to deny the contractor reimbursement for costs incurred in good faith on the changed work, especially where the extra effort involved is incorporated in the contract end product and USAMRDC gains the benefit of the change. Therefore, the COR's action in such a case constitutes an improper and unauthorized obligation of public funds. Remember, only the CO may obligate the Government to pay private parties for services or products provided to USAMRDC. Such unauthorized action may be at the COR's personal expense.

How To Avoid Constructive Changes

Careful preparation of initial contracts, by removing ambiguities or inconsistencies from the specifications, is the first step in avoiding constructive change. This includes careful drafting of a formal modification. The Government often does not consider the magnitude of the effect a modification will have on the contractor. For example, when an equitable adjustment is negotiated, the Government does not allow the contractor enough additional time to perform. This, in turn, creates a constructive change for which an adjustment will become due.

The second step in avoiding constructive changes is for the COR to know what the contract requires. Both erroneous interpretation of specifications and overly strict inspection tend to result from a failure by the COR to read the contract carefully. When decisions are made based on what "everybody" knows the specifications ought to say rather than on what they really do say, claims frequently result.

The third step is for the COR to keep proper records. For example, if, during an interim inspection, the COR tells the contractor that some aspect of performance is inadequate, the aspect should be explained in writing, with a copy transmitted to the contractor through the CO.

Documentation of final inspections is also important. It is not sufficient to merely tell the contractor that the product is unacceptable. Specific problems should be identified in writing. Contractors can mistake a general comment about one way to correct a problem as specific direction that this is the only acceptable way. Good documentation can eliminate that sort of misunderstanding.

Finally, the COR must always act in good faith and must always follow Government procedures. Do not try to get something for nothing. Do not try to get around the paperwork. The Government loses claims, along with the reasonable technical cooperation of its contractors, when the COR circumvents the required procedures and principles.

D.5 SOME COMMON USAMRDC CONTRACT ACTIONS

During the term of a contract, the typical Principal Investigator (PI) will make several requests of USAMRDC. These will range from permission to purchase the equipment shown in his budget, to seeking supplemental funds and extension of the contract terms. COR actions in handling these requests will vary somewhat according to procedures established by the Acquisition Management Liaison Office (AMLO) operation for each USAMRDC laboratory or institute. In general, all PI requests must be routed through the CO, who will forward them to the appropriate AMLO for coordination with the COR. A COR who receives requests directly from the PI will either notify the PI of the correct routing or send the request to his AMLO for entry into the system.

A PI request will sometimes result from discussions with the COR on various aspects of the PI's contract performance. This is a natural consequence of a working PI/COR relationship. However, the COR must be very careful that his discussions and suggestions are not interpreted by the PI as commitments. The PI must understand that his request of USAMRDC is just that. It will be considered in light of mission needs and, if approved, granted only through the CO.

Several months may elapse from the time a PI sends in his request until it becomes an active part of his contract. The mails, in-house distribution, COR and PO reviews, and the CO workload all have their effect on the response time to even relatively minor requests. The COR and the PI must realize this, and plan accordingly.

While the nature of the requests will vary, the need for COR study of these matters, the documentation requirements, and the routing of the request remains fairly consistent. Typically, COR approvals of requests for changes or modifications will require comments on the following:

- The scientific necessity for approving the request.
- The impact on the project if the request is not approved.
- The reason why this request was not reflected in the original budget.

The great majority of PI requests fall into a relatively few categories. Typical COR responses/actions to the most common of these are:

Request to purchase equipment listed in the original budget - While this is not a contract change, it is a requirement on all cost reimbursement contracts. This procedure serves two purposes. First, it allows DOD an opportunity to fulfill the PI need from equipment on hand. Second, it ensures that the PI is purchasing the approved equipment. COR approval indicates that the need for the requested equipment on the project still exists. The COR must be prepared to address a brand change or significant change in price.

Request for supplemental funds - Any proposed activity or purchase which will require funds in excess of those specified in the contract must be approved through a supplemental fund change to the contract. (Note that a change in the SOW may or may not be needed, as well.) If the request involves funds in excess of $1000, the COR must explain the need for the supplement. Coordination with and approval of other program officers is also necessary to provide for the accountability of program investments.

Request to extend the term of the contract - This type of request will be used to extend the contract by only several months. The basic purpose of the extension is to allow the PI more time to complete work on the original SOW. It is granted in cases where the PI has encountered unavoidable delays during the regular contract term. The request may or may not include the need for supplemental funds. It is important to note that, even if supplemental funds are not involved, an approved extension to the contract is needed in order for the PI to expend any remaining contract funds beyond the original termination date.

Request to rebudget funds - In the term of a contract, a PI will sometimes find that a portion of his funds is unspendable for their original intent. Excess personnel funds generated because one or more of the workers were not on the project in its first several months are an example. Frequently, the PI will ask that such funds be transferred or rebudgeted to another use in the project. The COR's responsibilities and actions in this matter are basically the same as if the PI was requesting a supplement; perhaps more so, since the PI is actually looking to bolster one phase of the budget at the possible expense of another.

Request for USAMRDC materiel and/or chemicals - The request will be forwarded to the COR through AMLO, as usual. The COR action will depend on the nature of the request. Ordinarily, only requests for materials not commercially available will be considered. An example would be drugs synthesized exclusively under USAMRDC sponsorship. Surety materiel is available only to contractors working at USAMRDC-approved facilities.

Request to change the SOW - Any significant change in the methods and/or goals of the original contract requires the PI to request that the SOW be amended to reflect the change. The COR, in coordination with appropriate PO, must determine whether a change in the SOW is needed, whether the proposed change is needed, and whether the proposed change might actually require a new or additional contract.

The documentation needed for COR and PO recommendations of these requests will depend on the magnitude of the changes sought. All contract modifications require submission of a USAMRDC Form 9, with a full description and justification for the change. Approvals for instrument purchases or re-budgeting can usually be handled as an endorsement to the subject DF from the CO.

E. CONTRACT PERFORMANCE PROBLEMS

The COR must monitor each of his contracts closely enough so that he may detect actual and potential problems early. In this way, corrective action(s) may be taken before the problems escalate to a point where the contract and research effort is jeopardized. Regular contact with the PI through reports, letters, telephone calls, and site visits is essential.

Remedial action outside of the direct PI/COR liaison generally requires several months to put into place. This applies whether or not the action needs to stop or improve the PI effort. Accordingly, AMLO and the CO must be advised of problems at the earliest possible time. They are the COR's principal source of recommended action.

E.1 COST OVERRUNS

Orderly management of USAMRDC contracts makes it imperative that unanticipated drains on budgeted funds be avoided. Funding unexpected overruns in a given contract can have adverse effects on funding of other contracts. Decisions of the Armed Services Board of Contract Appeals (ASBCA) have held the Government legally liable to pay cost-reimbursement type contractor costs incurred in excess of the contract limitation under the Limitation of Cost clause, notwithstanding that the Government had not "found" or decided to make available the additional funds. Technical personnel who knew the contractor was in an overrun position nevertheless had indicated that the Government expected the contractor to continue performance. The ASBCA held that absence of CO authority of such technical personnel would not necessarily defeat the contractor's claim. It has also held that contractual language disclaiming liability will not protect the Government when, by their course of conduct, the Government's technical representatives (COR) have shown disregard for the contract language and limitations. Government personnel are advised that encouraging a contractor to continue work in the absence of funds may result in a violation of 31 USC Sec. 665. Violators are subject to criminal penalties for knowing and willful over-obligation of funds, and administrative penalties (including separation) are provided for less flagrant violations.

When considering the reasons for cost growth, the first impression that comes to mind, particularly with the public, as led by legislators and the press, is that cost growth is the result of overruns because of gross mismanagement. There may well be mismanagement or inefficiencies involved, but more often they are responsible for a relatively small proportion of the cost growth. Typical causes of cost growth are:

- Planning Difficulties
    - Incomplete definition of work
    - Interface incompatibilities
    - Changes; failure to anticipate needs
    - Estimating uncertainties; poor estimating
    - Optimistic assumptions
- Risk Elements
    - Unforeseeable conditions
    - Unpredictable regulatory or funding delays
    - Unforeseen technical difficulties
    - Uncontrollable forces
    - Unanticipated economic conditions
- Management Inefficiencies
    - Disorganized work direction and productivity
    - Subcontracting
    - Unnecessary work or "gold plating"
    - Project control
    - Work load projections

E.2 INADEQUATE CONTRACTOR PERFORMANCE

In a delinquency or default situation, contractor performance is delayed, inadequate, or both. The COR must thoroughly understand the rights and responsibility of both the Government and the contractor so that he will do nothing that might be considered prejudicial to either party.

When unsatisfactory contract performance is identified, the COR should notify the CO promptly so that remedial steps can be taken. Silence on the part of the Government could be interpreted by the contractor as revised Government expectation of performance, which may differ from that stated in the contract. Such situations could adversely effect the Government's right to withhold payments, terminate for default, or otherwise exercise certain rights under the contract.

Unsatisfactory performance can be considered in degrees, and the Government's actions can be oriented to correct the unsatisfactory performance or to protect the Government's interest in the event of a contractor's default. Depending upon the CO's evaluation of the seriousness of the unsatisfactory performance he may:

- By letter or through a meeting, bring the particular deficiency to the attention of the contractor and obtain a commitment for appropriate corrective action;
- Extend the contract schedule if excusable delays in performance are involved;
- Withhold contract payments in cases where the contractor fails to comply with delivery or reporting provisions of the contract; or
- Terminate the contract for default.

After a complete review of the situation, the CO may send a notice of failure of performance to the contractor. This notice, which officially notifies the contractor of the delinquency, requires the contractor to inform the CO of the cause(s) of the delinquency so that a proper determination can be made concerning continuation or termination of the contract.

Without express authority from the CO to the contrary, the COR should have no contact with the contractor during this period. Any action that might encourage the contractor to continue performance may have the effect of waiving the Government's rights under the contract.

E.3 WITHHOLDING PAYMENT

All Government contracts contain a clause allowing the Government to withhold payments. A contractor's failure to either submit a report, or to perform or deliver services or work when required by the contract is to be considered a default in performance. In either circumstance, the CO is directed to immediately issue a formal "cure notice," which is to include a statement to the effect that contract payments will be withheld if the default is not "cured" or is not determined to be excusable. A "cure notice" is a formal notice from the CO pointing out a deficiency in contractor performance and directing that it be "cured" within a specified time, usually 10 days.

If the default is not determined to be excusable or a response is not received within the allotted time, the CO initiates withholding action on all contract payments and determines whether termination for default or other action would be in the best interest of the Government.

When determination is made that contract payments should be withheld, the CO should immediately notify the contractor in writing that payments have been suspended until the default or failure is cured.

E.4 TERMINATIONS

Situations may arise when the work contracted for does not run to completion. Two standard contract clauses are designed to cover this eventuality: the "Termination for Convenience of the Government" clause and the "Default" clause. Both types of terminations can be either partial or complete, that is, all or any part of the work can be subject to the termination. The portion that is not terminated must be completed by the contractor. The contractor has no contractual right to decide that the remaining work is insufficient to merit his attention and then opt not to continue with it. No matter what type of termination is issued, or the extent of the terminated portion of the work, the decision to terminate is a unilateral right of the Government.

Termination for Convenience

The Termination for Convenience clause gives the Government the right to cancel a contract when to do so is in the best interest of the Government, notwithstanding the contractor's ability and readiness to perform. Major reasons for terminations for convenience include the following:

- The item or service is no longer needed.
- The item has become technologically obsolete.
- General cutbacks in operations.
- Work under a cost contract does not appear promising.
- Allocated funds are needed for higher priority work.

Termination for convenience requires that a financial settlement be made for the work that has been accomplished under the contract up to the effective date of the termination. Settlements may be reached by negotiated agreement or by CO determination.

Following the termination, the Government and the contractor may need to reach an agreement on an equitable settlement. The CO evaluates the contractor's settlement claim and establishes the Government's position with respect to the various elements of cost or price included. A cost or price analysis must be performed and, in some cases, the contractor's books and records must be audited. A memorandum documenting the negotiations must be placed in the contract file.

Termination for Default

The Termination for Default clause allows the Government to terminate the contract when the contractor fails to make progress with the work or to perform any other contract requirements within the period provided by a "cure notice." The detailed conditions under which a contract may be terminated for default, and the procedures for doing this are set forth in Part 49 of the FAR. Once a CO has determined that it is necessary to invoke the Termination for Default clause, the COR should have no further contact with the contractor unless specifically directed to do so by the CO.

E.5 PROCEDURES FOR DISCONTINUANCE OF USAMRDC SUPPORT

This Command has always tried to deal with our community of contractors in an ethical and humane way, as well as meeting all the requirements of the Federal Acquisition Regulations (FAR). Execution of every contract, regardless of its purpose, involves people. When we do not continue a contract effort, we always try to give the contractor as much notice as possible to reduce the adverse impact on contractor employees.

When a decision is made not to exercise an option or apply incremental funds to an existing contract, or to terminate a contract, the AMLO shall notify the appropriate CO at least 90 days in advance. The CO will notify the appropriate AMLO by telephone or electronic transmission when notification is sent to the contractor's business office. The AMLO will notify the COR, who will telephone the contractor's PI to advise that research is to cease prior to the originally planned date. Wherever practicable, termination should take place on the date incremental funding was planned for application.

This procedure is intended to maintain a favorable relationship between USAMRDC and contract researchers, in order that they will be responsive to future Government needs. Should it not be possible to meet the 90-day period stipulated above, coordinations should be effected by telephone or electronic means, to provide the greatest possible advance notice.

E.6 RESOLVING DISPUTES

No matter how carefully a contract is negotiated and written, due to the complex nature of the Government contracting process and the involved relationship between the contractor and the Government, disputes can and often do arise. The Disputes clause included in all Government contracts is designed to ensure that disagreements between the Government and the contractor will not interfere with the scheduled performance of the contract. It also provides a channel through which disagreements and differences can be resolved by the persons directly involved.

The CO has wide powers to settle contractual matters. Some of the matters that may be settled by decision of the CO are -- making equitable adjustments pursuant to the Changes and Government Furnished Property clauses; reducing prices under the Inspection clause; and providing for reimbursement for extra work performed. If agreement can be reached between the two parties in regard to the equitable adjustments, additional reimbursement, or refunds required under any contract clause, a bilateral agreement may be negotiated between the two parties.

If agreement cannot be reached, these issues, as well as others involving disagreements, are resolved under the procedures set out in the Disputes clause.

The standard Disputes clause included in all Government contracts provides:

- That the contract is subject to the Contracts Disputes Act of 1978 (PL 95-563).
- For contractor claims of $50,000 or less, the CO must render a decision within 60 days. For contractor claims in excess of $50,000, the CO must decide the claim within 60 days or notify the contractor of the date when the decision will be made.
- The CO decision is final unless the contractor appeals or files a suit as provided in the Act.
- The authority of the CO under the Act does not extend to claims or disputes which by statute or regulation other agencies are expressly authorized to decide.
- Interest on the amount found due on contractor claims is paid from the date the claim is received by the CO until the date of payment.

- Except as the parties may otherwise agree, pending final resolution of a claim by the contractor arising under the contract, the contractor must proceed diligently with the performance of the contract in accordance with the CO decision.

F. AT THE END OF THE CONTRACT

F.1 INSPECTION AND ACCEPTANCE RESPONSIBILITIES

Before services or products required by the contract can be accepted, acceptability must be determined by review, test, evaluation, or inspection. These functions are performed by the COR, who then reports the results to the CO.

Final acceptance of the work effort by the CO concludes performance by the contractor, except for administrative details relating to contract closeout. After final acceptance, the contractor can no longer be held responsible for unsatisfactory effort, unless otherwise specified in the contract. Therefore, the CO must ensure that the work performed under the contract is measured against the work statement. If performance does not meet contract requirements, it is incumbent upon the COR to identify deficiencies and to advise the CO so that remedial action can be taken before final payment and contract closeout.

F.2 CONTRACT REVIEW AND ANALYSIS

At the conclusion of a research effort, or at a significant intermediate milestone during a long-time research study, a Review and Analysis may be conducted following submission of the contractor's draft final report, but before that report is finalized. The investigator will make a formal presentation at the meeting. The format, level of detail, and emphasis of the presentation will be mutually decided between the COR and the PI. Attendees will include the PI and key staff members, in-house personnel and consultants who participated in the study's technical monitorship, representatives from user agencies for which the study was conducted, and other individuals, technical experts, or contractors who have a substantial interest in the research effort. The Review and Analysis serves three primary functions:

- Since it is conducted before the finalization of the contractor's report, it serves as a forum during which modifications to the final report can be discussed. These changes could include improvements in the technical analyses and interpretation of alternative methods of data presentation to facilitate user needs.

- The Review and Analysis accelerates the transfer of a study's results to the user and insures that the user is fully aware of both the impact and limitations of the study's findings. To achieve this, the meeting must be carefully planned to emphasize those items of interest to the user. Prior to the meeting, all attendees should be provided with a copy of the draft final report. The agenda should provide ample time for discussions of both technical details and impact of the findings.

- A final function of the Review is to evaluate the adequacy of the contractor's study to satisfy the user's needs. Critical review may be made of the contractor's performance and the necessity for additional research efforts to address unforeseen problem areas.

Following the Review and Analysis, the contractor will be provided with comments for modifications to the final report. If the modifications are major, a second draft for review may be required. If changes are minor, the contractor will be authorized to proceed with preparation and distribution of the final report.

F.3 CONTRACT CLOSEOUT

A contract is completed when all services have been rendered; all articles, material, report data, exhibit, etc., have been delivered and accepted; all administrative action accomplished; and final payment made to the contractor. Contract closeout actions are primarily the responsibility of the CO, but the assistance of the COR will be required to certify that all services have been rendered in a satisfactory manner and that all deliverables are complete and acceptable. The COR's assistance is indispensable when disputes, litigation, patent and copyright problems, etc., are involved. Poor performance by a contractor shall be documented, and detailed information provided to the CO for inclusion in a data base on USAMRDC contractors. When a contractor fails to meet goals, is delinquent in performance or delivery of data, or is generally non-responsive to requirements, these facts shall be considered in selections to perform on future USAMRDC contracts. Centralized data in USAMRAA will permit determinations of responsibility and responsiveness of contractors by the CO.

Upon completion of the contract, the CO must ensure or determine that:

- All services have been rendered, and accepted in writing by the COR;

- All articles and reports have been delivered, and accepted and approved in writing by the COR;

- All payments and collections have been made;

- Release from liabilities, obligations, and claims have been obtained from the contractor;

- Assignment of refunds, credits, etc. have been executed by the contractor;

- All administrative actions have been accomplished, including the settlement of disputes, protests, and litigation; determination of final overhead rates; release of funds; and disposal of property etc.;

- The COR has reviewed and made appropriate recommendations regarding any invention disclosures submitted by the contractor; and

- The contract file is complete and properly documented.

The file must include all inspection and acceptance documents, or a statement from the COR that all services and deliveries required by the contract have been performed or delivered in accordance with the terms of the contract and are acceptable to the Government. All discrepancies with contract requirements must be reconciled before the contract file is closed.

All public vouchers and contractor invoices that support advance, partial, progress, and final payments must be included. The contract file must also include written documentation related to settlement of any questions of disallowed or suspended costs or any discrepancies between payments and deliveries or performance, and between billings and payments.

If there was a subcontract, the file must contain subcontract approvals, including the letter or document of approval and the subcontract review memorandum. If approval of individual subcontracts is waived by approval of the contractor's purchasing system, approval must be included in the contract file. The file must also contain documentation of the resolution of disputes between prime and subcontractors, unless the prime contractor releases the Government from any obligation relating to the subcontractor claim.

Contract modifications that result from additions or changes to the terms and conditions must be included, as must inventory and records of disposition of Government-owned property. All clearance and reports relating to inventories, patents, royalties, copyrights, publications, tax exemptions, etc. should go into the file. Also the file must contain copies of inquiries and answers and reports to and from sources such as the Congress, the General Accounting Office, audit activities, etc.

F.4 CONTRACT AND PROJECT FILES

The FAR is quite specific about the requirements for establishing, maintaining, and disposing of contract files. These files must be maintained by the CO and they must be sufficient to constitute a complete history of the transaction for the purpose of:

- Providing a complete background as a basis for informed decisions at each step in the acquisition process;
- Supporting actions taken;
- Providing information for reviews and investigations; and
- Furnishing essential facts in the event of litigation or congressional inquiries.

It is USAMRDC policy that the COR or appropriate AMLO maintains a file on each contract. That file will enhance the COR's ability to effectively and efficiently monitor a contractor's progress, as well as provide data that will ensure continuity in contract administration should there be a change in COR during the course of a contract. Suggested contents are listed under COR Contract File on page 71 of this Guide.

SECTION VII: STANDARDS OF CONDUCT

Each year, the Federal Government spends in excess of $100 billion on acquisitions. With this magnitude of spending, it is inevitable that public officials who participate in the acquisition process will come under close public scrutiny and may occasionally be subjected to situations that may lead to improprieties, abuse of office, fraud, or theft.

By virtue of their unique position and responsibilities regarding the acquisition process, COR are particularly susceptible to improper influences from those who seek to do business with the Government. Therefore, COR should take particular care to familiarize themselves with regulations governing standards of conduct for Government employees. In particular, the reader is referred to AR 600-50, "Standards of Conduct", which must be read semiannually by all individuals who have a Government role in the procurement process.

A. GRATUITIES

Gratuities are defined as gifts, entertainment, or favors generally given to enhance the relationship between the offeror and the Government employee, rather than to bribe. Government employees are prohibited from accepting gratuities on the premise that "gifts, entertainment, or favors," no matter how innocently offered and received, may be a source of embarrassment both to USAMRDC and to the employee involved. Accepting gratuities might give the impression that the objective judgement of the recipient has been affected and could impair public confidence in the integrity of the relationship between USAMRDC and the private organization.

B. CONFLICT OF INTEREST

Executive Order (EO) 11222 deals with Government employees' participation in matters affecting a personal financial interest. Basically, the policies in this area prohibit an employee from participating "personally and substantially" as a Government employee in a matter, procedure, determination or contract in which any of the following individuals or organizations has a financial interest:

- The employee, the employee's spouse, or the employee's minor child;
- An organization in which the employee serves as an officer, director, trustee, partner, or employee; or
- A person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment.

Criminal penalties may be imposed under 18 USC 208 for violations of these prohibitions.

Executive Order 11222 extends this policy somewhat in providing that "an employee need not have a financial interest that actually conflicts with his or her duties to violate the prohibition of Executive Order 11222. Any financial interest that could reasonably be viewed as an interest which might compromise the employee's integrity, whether or not this is in fact true, is subject to this prohibition."

In acquisition matters, this means that a CO, COR, PO, proposal evaluator, source selection official, or any other Government official having a financial interest in one or more offerors responding to a proposal would be prohibited from engaging in decisions, approvals, disapprovals, recommendations, and investigations; providing advice; or making any other significant effort regarding the acquisition process. This includes participating in drafting specifications or SOW for acquisitions when the drafter expects a company in which he has a financial interest to submit a proposal.

Generally, employees who will have a conflict of interest, as described above, must disqualify themselves from participating in the acquisition process. However, this discussion of conflict of interest is only a general treatment of a fairly complex subject. Government employees who are required to participate in a particular procurement that may present them with a conflict of interest should refer to the applicable sections of Executive Order 11222 for full details.

A useful summary entitled "Standards of Conduct and Conflicts of Interest Restrictions" is given in Appendix I.

C. USE OF OFFICIAL INFORMATION

The public interest requires that certain information in the possession of the Government be kept confidential, and released only with general or specific authority under DOD or other regulations. Such information may involve the national security or be private, personal, or business information that has been furnished to the Government in confidence. In addition, information in the possession of the Government and not generally available may not be used for private gain.

Most of the prohibitions against use of official information are applicable to the regulations governing conflict of interest. In addition, regulations governing use of official information prohibit an employee from allowing others to make use of official information. Employees shall not, directly or indirectly, make use of official information not made available to the general public, for the purpose of furthering any private interest.

D. PROTECTING THE INTEGRITY OF THE ACQUISITION PROCESS

The term, "integrity of the acquisition process," in this instance, means allowing private sector firms to compete for the Government's business on a scrupulously fair basis. The emphasis here is on the word "fair." Not only is fairness a prerequisite in Government acquisition due to the Government's unique position as representative of the American people, but fairness also helps ensure that the Government will obtain its supplies and services at the best price available.

Government personnel who are associated with the acquisition process have a responsibility to protect its integrity, maintaining fairness in the Government's treatment of all vendors. There are numerous points within the acquisition process where the potential to lose this fairness is high. For example:

- **Pre-solicitation.** Allowing a vendor or vendors access to information on a particular acquisition (especially the specification or work statement) before such information is available to the business community at large may give the vendor(s) receiving the information an unfair advantage over others.
- **Specifications.** Intentionally writing an unnecessarily restrictive specification or work statement that would effectively exclude the products or services of a vendor and/or increase the prospects for award to another vendor is an obviously unfair practice. Not only does this give advantage to one or more vendors over others, but it also restricts competition and makes it more likely that the Government will ultimately pay a higher price.
- **Confidentiality of proposals.** From the time proposals are received in response to a solicitation until a contract is awarded, all information concerning the proposals, including their number and submitters, must be held in strict confidence. Should this information become available to one or more offerors, it could put that offeror(s) at a distinct advantage.

E. FRAUD IN GOVERNMENT CONTRACTS

One of the cornerstones of the Federal procurement system is the requirement that Government contracts shall be awarded, to the greatest extent possible, on the basis of free and open competition. More than a dozen Federal statutes define and specify the penalties for the varied methods according to which the Government and its contracting process can be defrauded or corrupted. Department of Justice experience shows that violations of those statutes can occur in all phases of the contracting process;

involve both contractor and government employees; and, entangle people who have no criminal intent.

The well-meaning Government program planner and executor should be aware of the indicators of fraud if he is to ensure integrity of the contract process and avoid violating the fraud statutes. A thorough coverage of this topic is given in a booklet entitled "Indicators of Fraud in Department of Defense Procurement", issued by the DOD Office of Inspector General, and available in each AMLO. The thrust of the booklet is on contractor fraud, but a potential for Government employee involvement is well covered.

Common sense is probably the keyword for the typical COR or PO in meeting the intent of the fair and open competition principle. This might be seen in the following indicators of possible fraudulent actions:

- The needs for a contract are not adequately or accurately developed.
- Defining needs in ways that can be met only by certain contractors.
- Defining SOW and specifications to match the capabilities of a single contractor.
- Using SOW and specifications developed by or in consultation with a preferred contractor.
- Placing restrictions on a solicitation that tend to unnecessarily restrict competition.
- Falsifying statements to justify sole source procurement.
- Acquiring or holding significant financial interest in a bidding or contractor company.
- Unauthorized release of information to a bidder or others.
- Using biased criteria and evaluators.

APPENDIX A : FORMAT FOR JUSTIFICATION AND APPROVAL FOR OTHER THAN FULL AND OPEN COMPETITION.

1. **Contracting Agency** - Specify the contracting agency responsible for this action.

2. **Description of Action** - Describe the nature of the contractual action for which approval is requested (i.e., new contract, modification). Include type of contract, type of funds to be used (R&D, PA, OMA) and estimated share and ceiling arrangements, when applicable.

3. **Description of Supplies/Services** - Describe the supplies or services to be acquired. Include the estimated total value (including options if any).

4. **Authority Cited** - Identify the statutory authority, FAR title and FAR citation permitting other than full and open competition.

5. **Reason for Authority Cited** - Describe how this action requires the use of authority cited. If applicable, identify the proposed or potential contractor(s) and include a discussion of the proposed contractor's unique qualifications for fulfilling the contract requirements. If the authority is urgent, include the required delivery schedule and leadtimes involved.

6. **Efforts to Obtain Competition** - Describe efforts made to ensure that offers are solicited from as many potential sources as is practicable. Also describe the extent of effective competition anticipated for this acquisition.,

7. **Efforts to Increase Competition** - Include a statement of the actions taken (or to be taken) to increase competition before any subsequent acquisition of the supplies or services is required. There may be instances where it is not possible to compete the current acquisition; explain how competition will be increased or enhanced for the required supplies or services (to include break out or other considerations). If the requirement is a repair part, address whether or not it has been screened under DAR Supplement Number 6. If screening has occurred, provide the Acquisition Method Code (AMC) and Acquisition Method Suffix Code (AMSC). Provide approximate date of technical data package (TDP) availability.

8. **Market Survey** - Describe the extent of the market survey (FAR 7.101) conducted to identify all qualified sources and the results thereof. Or, only if justified, reasons why one was not conducted.

9. **Interested Sources** - Include a listing of the sources that expressed written interest in the acquisition. If 10 U.S.C. 2304 (c)(1) is the intended authority, explain why such other sources responding to the synopsis were rejected. (Note: A synopsis

should be issued as soon as the procurement package is received so contractors may respond while the J&A is being written, since the synopsis and its results shall have occurred prior to processing the J&A in accordance with FAR 6.302-1(c)(2).) If applicable, clearly state that "To date, no other sources have expressed an interest in writing." Also state that the notices required by FAR 5.201 shall be/have been published and any bids and proposals received shall be considered. If a CBD notice will not be published, state which exception in FAR 5.202 applies.

10. **Other Factors** - Discuss any other factors supporting the use of other than full and open competition, such as:

a. Procurement history. The following items of information are expected.

1. Contract numbers and dates of the last several awards.
2. Competitive status of these actions.

3. Authority for less than full and open competition previously used.

4. If a J&A was prepared to support the immediately prior buy, briefly describe the Actions to Increase Competition (paragraph 7) mentioned in that prior J&A, and explain the results thereof.

5. If any prior award was fully competitive, explain the changed circumstances in detail.

6. Explain any unusual patterns which may be revealed by the history, e.g., several consecutive, urgent buys.

7. If a J&A was prepared to support the immediately prior buy, briefly describe the circumstances justifying the last buy and whether there have been any significant changes.

b. The required information may not always be easily accessible; however, reasonable efforts to retrieve it are expected. Resources include past contract files, and for AMC, the Commodity Command Standard System (CCSS) files (particularly the Procurement History File) and, in unusual cases, the Competition Management Office may be of assistance. When data are lacking, fill in as much as is available and write "unknown" in the appropriate areas. That way, a reviewing office with different resources or point of view may be able to fill in the mission information.

c. Acquisition Data Availability - Explain why technical data packages, specifications, engineering description, statements of work or purchase descriptions suitable for full and open competition have not been developed or are not available. Describe actions taken or planned to remedy this situation.

d. Follow-on Contracts - When FAR 6.302-1(b)(2) is cited, include an estimate of the cost that would be duplicated and the basis and derivation of the estimate.

e. Unusual and Compelling Urgency - When FAR 6.302-2 is cited, provide data, estimated cost or other rationale as to the nature and extent of the harm to the Government. If the inclusion of first article testing is the principal reason for not awarding the contract on a full and open basis, clearly describe the reasons that first article testing is required on this procurement and why other means of assuring quality are not being used.

f. Subcontracting Competition - In single source situations, address efforts to be taken by the Government to assure that the prime contractor obtains as much competition as possible in its subcontracting.

11. **Technical Certification** - Include the following statement: "I certify that the supporting data under my cognizance which are included in the J&A are accurate and complete to the best of my knowledge and belief."

Name:____________________ Date:____________________

Title:____________________ Signature:____________________

12. **Requirements Certification** - Include the statement in para. 11 above.

Name:____________________ Date:____________________

Title:____________________ Signature:____________________

13. **Fair and Reasonable Cost Determination** - Include the following determination: "I hereby determine that the anticipated cost for this contract action will be fair and reasonable." Provide the basis for this determination (e.g., describe techniques to be used to determine fair and reasonable price, such as cost analysis, price analysis, audit, should cost, independent Government estimate, etc.).

14. **Procuring Contracting Officer Certification** - This person shall be the contracting officer who will sign the contract resulting from this J&A. Include the following statement: "I certify that the facts and representations under my cognizance which are included in this J&A are accurate and complete to the best of my knowledge and belief."

Name:____________________ Date:____________________

Title:____________________ Signature:____________________

APPROVAL

Based on the foregoing justification, I hereby approve the procurement of (state equipment/services being procured) on an other than full and open competition basis pursuant to the authority of 10 U.S.C. 2304(c)( ), subject to availability of funds, and provided that the services and property herein described have otherwise been authorized for acquisition.

Date:______________________ Signature:____________________________

Approval of the Justification.

For the Army, the competition advocate in FAR 6.304(a)(2) is the advocate at the HCA level.

For the Army, Head of the Procuring Activity in FAR 6.304(a)(3) is the HCA. The designee, if any, shall not be at a level below the competition advocate in (a)(2) above.

Each request for approval by the Senior Procurement Executive (ASA(RDA)) shall be forwarded by letter of transmittal through procurement channels to the addressee in AFARS 1.290(b)(6). The letter of transmittal signed by the contracting officer shall recommend Secretarial approval of the attached justification and shall bear the unqualified endorsement of the HCA. Each justification shall be submitted to reach the approving authority at least 20 working days prior to the scheduled release of the solicitation. The solicitation shall not be released until the justification is approved in writing.

Requests for approval of class justifications shall be supported with detailed rationale for necessity of class justification and the method to be used to ensure its proper use (such as reviews by counsel/competition advocate of individual actions).

Requests for Head of Procuring Activity or Competition Advocate approval shall be submitted to the approving authority before release of the solicitation. The solicitation shall not be released until the justification is approved in writing.

APPENDIX B: USE OF HUMANS AS RESEARCH SUBJECTS IN THE EXTRAMURAL RESEARCH PROGRAM

I. Purpose: This is to establish uniform procedures and responsibility for review of the use of humans as research subjects, negotiation of provisions, and administration of research projects in the extramural program.

II. References:

1. 45 CFR 46 HHS Regulation on Protection of Human Subjects;
2. 10 U.S.C. Section 980 DOD Policy on Informed Consent;
3. 21 CFR 312 Investigational Drugs and Vaccines;
4. 21 CFR 812 Investigational Medical Devices;
5. DOD Directive 6465.2 Organs and Tissues Obtained from Autopsy;
6. DOD Directive 3216.2 Protection of Human Subjects in DOD-Supported Research;
7. Federal Acquisition Regulation (FAR) 52.228-7 Insurance Liability to Third Persons and FAR 31.109 Advance Agreements
8. USAMRDC Regulation 70-25 Use of Human Subjects in Research, Development, Testing and Evaluation; and
9. USAMRDC Broad Agency Announcement (BAA).

III Objectives:

1. Safeguarding the rights and welfare of human subjects participating in research and development supported by contracts, grants and orders awarded by U.S. Army Medical Research and Development Command (USAMRDC) is of utmost concern to the Command, and is primarily the responsibility of the contractor or recipient who receives or is accountable to USAMRDC for the funds awarded for the support of the project. However, the sensitivity of such research necessitates that the Command exercise prudence in its oversight responsibilities. The procedures employed shall be flexible and tailored to the requirements of the specific acquisition.

2. It is the policy of USAMRDC that the Department of Health and Human Services (HHS) Regulation on Protection of Human Subjects shall be adhered to by USAMRDC contractors and recipients, with the addition of the following specific DOD/USAMRDC requirements.

a. Informed consent must be obtained in advance from the subject, or if intended to be beneficial to the subject, may be given in advance by the subject's legal representative.

b. Contractors and recipients shall provide medical care to research subjects for injury or disease which is the proximate result of participation in the research.

c. Prisoners of war shall not be used as research subjects.

d. Organs, tissues, or tissue fluids obtained from autopsy shall not be used for research or investigational purposes without the expressed consent of the next of kin. It should be noted that a general autopsy consent may not, in itself, be sufficient. If autopsy tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.

e. Organs, tissues, or tissue fluids obtained from a surgical procedure shall not be used for research or investigational purposes without the expressed consent of the patient or patient's legal representative. It should be noted that a consent to perform surgery may not, in itself, be sufficient. If excised tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.

f. Anatomical substances linked by identifiers to a particular person and used for research shall be donated for the purpose of research, and shall be lawfully acquired. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and the donor shall relinquish all ownership and/or rights to the substance.

g. The USAMRDC may inspect contractor records concerning human use.

h. Use of prisoners as research subjects shall follow 45 CFR 46, Subpart C.

i. Studies conducted outside the U.S., its territories or possessions, which involve the use of non-U.S. citizens as subjects, in addition to compliance with 45 CFR 46 and special DOD requirements, shall comply with the laws, customs, and practices of the country in which the study is to be conducted. The minimum standards to be adhered to are contained in the Declaration of Helsinki (Tab D). The research proposal submitted for approval will document this action. In exceptional circumstances where laws, customs or practices of the country involved take exception to particular procedural requirements of this provision (as, for example, the documentation of informed consent or the procedures by which it is obtained), specific approval will be obtained from the Commander, U.S. Army Medical Research and Development Command as an integral part of the proposal review and approval process.

j. None of these provisions apply to epidemiological surveys involving no more than minimal risk.

IV. Goals:

1. The Human Use Review and Regulatory Affairs Office (SGRD-HR) shall be responsible for all aspects of the USAMRDC extramural program involving the use of humans in research and testing, and use of human anatomical substances. SGRD-HR is specifically responsible for:

a. Review of any proposal and consent form, contract, subcontract, grant, intragovernmental transfer of funds order, or modification which involve the use of humans or human anatomical substances. Review shall ensure:

(1) that pertinent DOD directives, Army Regulations, and HHS regulations are not violated;

(2) that appropriate validation of the human use process has occurred, and;

(3) that the recipient or contractor has an assurance of compliance with 45 CFR 46 satisfactory to the HHS, or has provided sufficient information for negotiation with the USAMRDC of a special assurance of compliance.

b. Development, in coordination with the U.S. Army Medical Research Acquisition Activity (SGRD-RMA), of special provisions to be included in RFPs, contracts, and grants. Development, in coordination with the Acquisition Management Office (SGRD-ACQ), of special provisions to be included in the BAA and intragovernmental transfer of fund orders.

c. Participating in negotiations (in conjunction with SGRD-RMA or SGRD-ACQ) with prospective contractors and other Government agencies for the development of special assurance of compliance with HHS 45 CFR 46. The SGRD-HR shall be the final approval authority for special assurances.

d. Review and approval of proposals recommended for inclusion in the competitive range as a result of solicitations, and its accompanying consent form. Where applicable, advertisements used to recruit subjects will be reviewed.

e. Assuring that all parties (e.g., contracting officer's representative (COR), Project Manager and Product Manager (PM), SGRD-ACQ, AMLO, and SGRD-RMA) are kept informed regarding issues relative to the use of humans.

f. Monitoring contracts, grants, and orders funded by USAMRDC by means of documentation review or site survey (pre- and post-award) as required.

g. Receiving reports of research related illnesses or injuries from principal investigators.

2. The SGRD-RMA shall be responsible for the following concerning the use of humans as research subjects or the use of human anatomical substances:

a. Negotiation, in conjunction with SGRD-HR, of special assurances of compliance with regulations with prospective contractors.

b. Development, in coordination with SGRD-HR, of special provisions to be included in RFPs, contracts and grants.

c. Contract administration to assure compliance with contract or grant terms.

d. Approval of use of prisoners as research subjects, after review and approval of the Command Judge Advocate and SGRD-HR.

3. The SGRD-ACQ shall be responsible for the following concerning the use of humans as research subjects:

a. Issuing required changes to this procedure.

b. Negotiation, in conjunction with SGRD-HR, of special assurances of compliance with regulations with other Government agencies.

c. Development, in coordination with SGRD-HR, of special provisions to be included in intragovernmental transfer of fund orders.

d. Approval of use of prisoners as research subjects, after review and approval of the Command Judge Advocate and SGRD-HR.

e. Administration of intragovernmental orders to assure compliance with the order.

4. The U.S. Army Medical Materiel Development Activity shall assist and participate with SGRD-HR, SGRD-RMA, and SGRD-ACQ on all matters pertaining to the use of humans as research subjects in programs under their cognizance.

5. The Office of the Command Judge Advocate shall advise SGRD-HR, SGRD-RMA, and SGRD-ACQ on all legal matters pertaining to

the use of humans as research subjects or the use of anatomical substances.

6. The appointed COR through the AMLO or PM shall assist and participate with SGRD-RMA, SGRD-HR, and SGRD-ACQ in administration of contracts, grants, and intragovernmental orders.

V. Procedures:

1. Proposed contracts, RFPs, and proposals received under the BAA, and proposals from other Government agencies which are recommended for funding shall be reviewed by SGRD-HR prior to submission to SGRD-RMA for procurement or to SGRD-ACQ for intra-government transfer of funds.

a. Clarifications or changes to proposals received in response to the BAA or from other Government agencies is the responsibility of SGRD-HR. Copies of all correspondence will be provided the affected AMLO.

b. Clarification or changes in RFPs and contracts is the responsibility of SGRD-HR. All communications with the contractor will be through SGRD-RMA.

2. To permit timely award of the contract, the USAMRDC Form 9 and documentation may be submitted by SGRD-HR to SGRD-RMA or SGRD-ACQ, even though all issues relating to the use of human subjects have not been resolved, on the condition that the Prohibition of Use of Human Subjects provision will be included in the contract, grant, or order.

a. Comments on proposals submitted in response to specific RFPs shall be provided by SGRD-HR to SGRD-RMA prior to negotiation by SGRD-RMA with organizations in the competitive range. SGRD-HR shall provide SGRD-RMA recommendations for negotiation of provisions to be included in contracts to be awarded as the result of other than full and open competition, and provisions for changes or tasks after contract award.

b. Upon receipt of required information, SGRD-HR shall review and approve the appropriate provision in the contract, grant, or order.

c. SGRD-HR will review and approve task order protocols in accordance with the special provisions of the contract.

d. Upon resolution of all issues involving the use of humans in research, the clause entitled "Use of Human Subjects, Investigational Drugs, and Investigational Medical Devices" (Tab B) will be included in the contract.

3. Compliance by subcontractors with 45 CFR 46 and these procedures is the responsibility of the prime contractor, subject

to the following:

a. Subcontracts shall contain the prime contract clause Prohibition of Use of Human Subjects (Tab A) or Use of Human Subjects, Investigational Drugs, and Investigational Medical Devices (Tab B). The proposed subcontract and assurance of compliance with 45 CFR 46 satisfactory to the HHS, or sufficient information for negotiation with USAMRDC of a special assurance of compliance, shall be submitted to SGRD-RMA for review and approval by SGRD-HR prior to award of the subcontract, or use of humans as research subjects.

b. The SGRD-RMA will obtain comments and approval of SGRD-HR prior to SGRD-RMA approval of the subcontract or use of humans, or negotiation of a special assurance with the subcontractor.

c. The prime contractor shall be involved with and participate in all discussions and negotiation. Responsibility for compliance with 45 CFR 46 and this procedure shall be the responsibility of the prime contractor and subcontractor(s) utilizing humans as research subjects. Subcontractors shall have Institutional Review Boards and follow 45 CFR 46, except under unusual circumstances where SGRD-HR and SGRD-RMA (or SGRD-ACQ) approve the prime's assuming responsibility for the subcontractor in this regard.

4. All contract administration is the responsibility of SGRD-RMA. The requirement for site visits, extend of examination of records, and discussions with researchers and research subjects shall, except under unusual circumstances, be coordinated between SGRD-HR, SGRD-RMA (or SGRD-ACQ), AMLO and the COR or PM. Copies of correspondence and telephone memoranda shall be exchanged between SGRD-HR, SGRD-RMA (or SGRD-ACQ) and the COR and AMLO or PM to assure awareness of human use issues. If the contracting officer, in consultation with SGRD-HR, determines that the contractor is not in compliance with the requirements of the provisions in Tab B, the contracting officer may suspend work and further payment until corrections are made by the contractor.

5. All contracts, grants, and intragovernmental orders which involve the use of humans shall:

a. Contain the provision (Tab A) to prohibit the use of humans as research subjects, or

b. Contain the provision (Tab B) governing the use of human subjects, investigational drugs or vaccines, and investigational medical devices, and/or

c. Contain the provision (Tab C) governing the use of donated anatomical substances.

d. Be reviewed and approved by SGRD-JA prior to award.

e. Be reviewed and approved by SGRD-HR prior to award.

6. Due to the fact that DOD policy requires the contractor or recipient to provide necessary medical care of research subjects, requests may be made by prospective contractors or recipients for assurance of future funding for certain liabilities, as set out in FAR 52.228-7(c)(2). Since the Government's liability is subject to the availability of funds at the time the contingency occurs, to cover such a contingency, an advance agreement (pursuant to FAR 31.109) may be negotiated to recognize costs, associated with such medical care, which exceed those covered by the contractor's insurance required by the contract. Such allowable costs, however, may not exceed the total amount of funds obligated by the Government to the contract. It is the responsibility of the contractor or recipient to initiate a specific request for funds to pay premiums for additional insurance coverage, or the costs of medical care required as a result of research performed under the contract, grant or order. Approval of the Secretary of the Army to indemnify a contractor or grantee against unusually hazardous risks may be requested pursuant to DOD FARS 35.070. Such requests shall only be made after receipt of proof the risk cannot be compensated by insurance or otherwise.

TAB A

Prohibition of Use of Human Subjects

Notwithstanding any other provisions contained in this contract or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of human subjects in any manner whatsoever. In the performance of this contract, the contractor agrees not to come into contact with, use or employ, or subcontract for the use of employ of any human subjects for research, experimentation, tests or other treatment under the scope of work as set out in the contract without express written approval from the contracting officer.

TAB B

USE OF HUMAN SUBJECTS, INVESTIGATIONAL DRUGS AND VACCINES, AND INVESTIGATIONAL MEDICAL DEVICES.

a. Definitions

(1) Subject at risk means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted

methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

(2) Investigational drugs and vaccines means those new drugs and vaccines restricted by the Federal Food, Drug, and Cosmetic Act to be used by or under the supervision of an investigator pursuant to a Notice of Claimed Investigational Exemption for a New Drug (IND).

(3) Investigational medical devices means those devices which are not generally recognized as safe and/or effective, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in, or research on, humans where the research is usually (but not necessarily) for the purpose of determining whether or not the device is safe and/or effective.

b. None of these provisions applies to epidemiological surveys which involve no more than minimal risk.

c. Requirements for the Use of Humans

(1) Safeguarding the rights and welfare of subjects at risk in activities supported by this contract is primarily the responsibility of the contractor. Compliance with this contract will in no way render inapplicable pertinent federal, state, or local laws or regulations. In order to provide for the adequate discharge of this institutional responsibility, it is the policy of the U.S. Army Medical Research and Development Command (USAMRDC) that no activity involving human subjects under this contract shall be undertaken unless an Institutional Review Board (IRB) has reviewed and approved such activity.

(2) The institution shall have provided to USAMRDC a written assurance that it will abide by the policy for the protection of human subjects as contained in 45 CFR 46. When an institution has an assurance of compliance satisfactory to the Department of Health and Human Services (HHS), evidence of IRB approval of the study shall have been accomplished by submission to USAMRDC of an executed HHS Form 596. For an institution without a HHS approved assurance of compliance, an assurance concerning the protection of human subjects shall have been negotiated with the USAMRDC Contracting Officer, and IRB approval given.

(3) In addition to the requirements of Title 45, Part 46 of the CFR, the following shall apply to all USAMRDC contracts supporting research, development, and related activities:

(a) Informed consent must be obtained in advance from a subject at risk, or in the case of research intended to be beneficial to the subject, a legal representative of the subject may give informed consent in advance of the research.

(b) The contractor shall provide for all necessary medical care of subjects at risk for injury or disease which is the proximate result of participation in the research.

(c) Prisoners of war shall not be used under any circumstances.

(d) Use of prisoners as research subjects shall have been specifically approved by the USAMRDC Contracting Officer.

(e) Studies conducted outside the United States, its territories or possessions involving non-U.S. citizens shall be conducted in compliance with all laws, customs, and practices of the country in which the study is to be conducted or this contract provision, whichever is more stringent, shall take precedence. The research shall meet the same standards of ethics and safety that apply to research conducted within the U.S. involving U.S. citizens.

(4) In addition to the requirements noted above, a copy of the protocol and informed consent for each phase of a study will be forwarded to the Commander, U.S. Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, MD 21701-5012. If available, a copy of the local IRB review and approval should be provided. Research involving the use of human subjects may not commence until approved by the Contracting Officer.

d. Requirements for the Use of Investigational Drugs and Vaccines

The contractor shall comply with 21 CFR 312 for the study and evaluation of those new drugs restricted by the Federal Food, Drug, and Cosmetic Act. The Drug shall be used by, or under the supervision of an investigator pursuant to a Notice of Claimed Investigational Exemption for a New Drug (IND). A copy of the current applicable forms as related under Part 312 shall have been provided with the contractor's proposal.

e. Requirements for the Use of Investigational Medical Devices

The contractor shall comply with 21 CFR 812 for the study and evaluation of those devices which are not generally recognized as safe and/or effective, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in, or research on humans. Should the contractor propose to use an investigational device in the research, he shall provide with his proposal a copy of Food and Drug Administration (FDA) approval of, or grant of waiver for, use of an investigational device exemption (IDE).

f. Requirements for Reporting and Documentation:

(1) Immediate telephone notification shall be given to the USAMRDC Human Use Review and Regulatory Affairs Office of any significant adverse reactions. (Telephone weekdays, Area Code 301/663-2165; nights, weekends, and holidays, the Duty Officer Telephone Area Code 301/663-7114.)

(2) Copies of all documents presented or required for initial and continuing review by the IRB, e.g., Board minutes pertaining only to the contract, record of subject's consent, transmittals on actions, instructions, and conditions resulting from IRB deliberations addressed to the activity director, are to be retained by the contractor for at least three years after completion of the research. All documents shall be accessible for inspection during normal working hours, by the USAMRDC Contracting Officer or authorized representative.

(3) Except as otherwise provided by law, information in the records or possession of the contractor which refers to or can be identified with a particular subject may not be disclosed except:

(a) with the consent of the subject or his legally authorized representative, or

(b) as may be necessary for the USAMRDC to carry out its legal responsibilities.

(4) Upon expiration or termination of this contract, a list of all unused test material shall be provided to the USAMRDC Contracting Officer.

(5) The contractor shall immediately notify the USAMRDC Contracting Officer, by telephone, of inquiries outside the Department of Defense concerning the use of human subjects under this contract. In addition, the Contracting Officer shall be notified as soon as possible of inspections of the facility or contract protocols by the FDA.

g. Subcontracts. Compliance by subcontractors with Code of Federal Regulations 45 CFR 46 and this contract provision is the responsibility of the prime contractor. All subcontracts which contain this contract provision shall be approved by the Contracting Officer prior to award. The requirements of paragraph c(2) above shall apply to subcontractors.

h. If at any time during performance of this contract, the contracting officer determines, in consultation with the USAMRDC Human Use Review and Regulatory Affairs Office, that the contractor is not in compliance with any of the requirements and/or standards stated in paragraphs c, d, and e above, the contracting officer may immediately suspend, in whole or in part, work and

(b) The contractor shall provide for all necessary medical care of subjects at risk for injury or disease which is the proximate result of participation in the research.

(c) Prisoners of war shall not be used under any circumstances.

(d) Use of prisoners as research subjects shall have been specifically approved by the USAMRDC Contracting Officer.

(e) Studies conducted outside the United States, its territories or possessions involving non-U.S. citizens shall be conducted in compliance with all laws, customs, and practices of the country in which the study is to be conducted or this contract provision, whichever is more stringent, shall take precedence. The research shall meet the same standards of ethics and safety that apply to research conducted within the U.S. involving U.S. citizens.

(4) In addition to the requirements noted above, a copy of the protocol and informed consent for each phase of a study will be forwarded to the Commander, U.S. Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, MD 21701-5012. If available, a copy of the local IRB review and approval should be provided. Research involving the use of human subjects may not commence until approved by the Contracting Officer.

d. Requirements for the Use of Investigational Drugs and Vaccines

The contractor shall comply with 21 CFR 312 for the study and evaluation of those new drugs restricted by the Federal Food, Drug, and Cosmetic Act. The Drug shall be used by, or under the supervision of an investigator pursuant to a Notice of Claimed Investigational Exemption for a New Drug (IND). A copy of the current applicable forms as related under Part 312 shall have been provided with the contractor's proposal.

e. Requirements for the Use of Investigational Medical Devices

The contractor shall comply with 21 CFR 812 for the study and evaluation of those devices which are not generally recognized as safe and/or effective, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in, or research on humans. Should the contractor propose to use an investigational device in the research, he shall provide with his proposal a copy of Food and Drug Administration (FDA) approval of, or grant of waiver for, use of an investigational device exemption (IDE).

urther payments under this contract until the contractor corrects uch noncompliance. Notice of the suspension may be communicated y telephone and confirmed in writing. If the contractor fails to omplete corrective action within the period of time designated in he contracting officer's written notice of suspension, the ontracting officer may terminate this contract in whole or in art, and the contractor's name may be removed from the list of hose contractors with approved policies on the use of human ubjects.

TAB C

USE OF ANATOMICAL SUBSTANCES

Any anatomical substance (organs, tissues, or tissue fluids) linked by identifiers to a particular person and used for research under this contract shall be donated for the purpose of research or investigation. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and shall relinquish all ownership and/or rights to the substance. All human anatomical substances used in research under this contract shall be lawfully acquired. It should be noted that a general autopsy consent form or a consent to perform surgery in and of themselves, may not be adequate. If excised or autopsy tissue is to be used, the protocol should include a copy of the consent from used to obtain the tissue.

TAB D

THE DECLARATION OF HELSINKI

1. BASIC PRINCIPLES

a. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

b. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment, and guidance.

c. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

d. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

e. Every biomedical research project involving human subjects would be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interest of the subject must always prevail over the interest of science and society.

f. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

g. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

h. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

i. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's given informed consent, preferably in writing.

j. When obtaining informed consent for the research project, the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

k. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

1. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

2. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (CLINICAL RESEARCH)

a. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

b. The potential benefits, hazards and discomforts of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

c. In any medical study, every patient--including those of a control group, if any--should be assured of the best proven diagnostic and therapeutic methods.

d. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

e. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

f. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

3. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (NON-CLINICAL BIOMEDICAL RESEARCH)

a. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

b. The subjects should be volunteers--either healthy persons or patients for whom the experimental design is not related to the patient's illness.

c. The investigator or the investigating team should discontinue the research if in his or her or their judgment it may, if continued, be harmful to the individual.

d. In the research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

ENDIX C: RESEARCH INVOLVING ANIMALS

General Information: Questions concerning animal use should directed to the USAMRDC Animal Use Review Office, in care of mmander, U.S. Army Medical Research and Development Command, TN: SGRD-AURO, Fort Detrick, Frederick, MD 21701-5012, elephone (301) 663-7567.

. Proposal Instructions: A proposal for research involving nimals is required by AURO to address all of the following oints:

1. Provide the rationale for the species and number of nimals to be used in the proposed study.

2. Detail the proposed use of the animals.

3. Describe the euthanasia methodology. Approved methods re listed in the "1986 Report of the American Veterinary Medical ssociation Panel on Euthanasia."

4. Provide one of the following:

   a. A copy of the contractor's Institutional Letter of ssurance of Compliance with Public Health Service Policy on umane Care and Use of Animals as outlined in the "NIH Guide for rants and Contracts," Special Edition on Laboratory Animal elfare, Volume 14, Number 8, June 25, 1985.

   b. Evidence that the contractor's facility is accredited by American Association for Accreditation of Laboratory Animal Care (AAALAC).

   c. A statement signed by an official of the contractor's Animal Care and Use Committee that the care and use of animals will be done according to NIH 85-23, 1985 Edition, "Guide for the Care and Use of Laboratory Animals," or other applicable Federal permits and regulations.

5. Provide evidence that the protocol was reviewed and approved by the contractor's Institutional Animal Care and Use Committee. If it was not possible to have the protocol reviewed by the Committee prior to submission of the proposal, then so state. Evidence of Committee review can follow but must be provided prior to award. RESEARCH WILL NO BE FUNDED WITHOUT EVIDENCE OF APPROVAL OF THE ANIMAL CARE AND USE COMMITTEE.

6. Provide assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

7. Provide a signed statement that the principal investigator understands and accepts the full responsibility for proper care and use of animals during the conduct of research outlined in the protocol.

C. Proposal and Performance Review: The USAMRDC procedure for animal use review is as follows:

1. The review of written research protocols involving the use of animals is the responsibility of the proposing organization's Animal Care and Use Committee (ACUC), as allowed by AR 70-18.

2. The USAMRDC Animal Use Review Office (AURO) will determine that the requirements of AR 70-18 and other applicable laws, regulations, directives, and guidelines have been addressed in the proposal, and that the proposal or protocol has been reviewed and approved by the proposing organization's ACUC. The AURO may choose a more extensive USAMRDC-sponsored review and/or site visit to obtain a better view of animal care and use in the proposed research.

3. The principal investigator has the ultimate responsibility of appropriate care and use of animals. The responsibility of monitoring on-going animal use research projects rests with the ACUC of the sponsored organization. The funding instrument (contract, grant, MIPR, etc.) will require that the principal investigator notify AURO in writing through the ACUC, of any significant changes. The sponsored organization's ACUC will stop the sponsored research project whenever violations relating to animal use occur.

4. The project Contracting Officer's Representative (COR) will devote a portion of each site visit to an animal care and use inspection in behalf of the AURO. The inspection will be of sufficient detail to enable the COR to identify significant problem areas relating to animal care and use. The AURO will be advised of the inspection results through a copy of the COR's trip report.

5. AURO site visits will be coordinated with the COR and appropriate U.S. Army Medical Research Acquisition Activity personnel.

APPENDIX D : TECHNICAL CRITERIA EVALUATION WORKSHEET

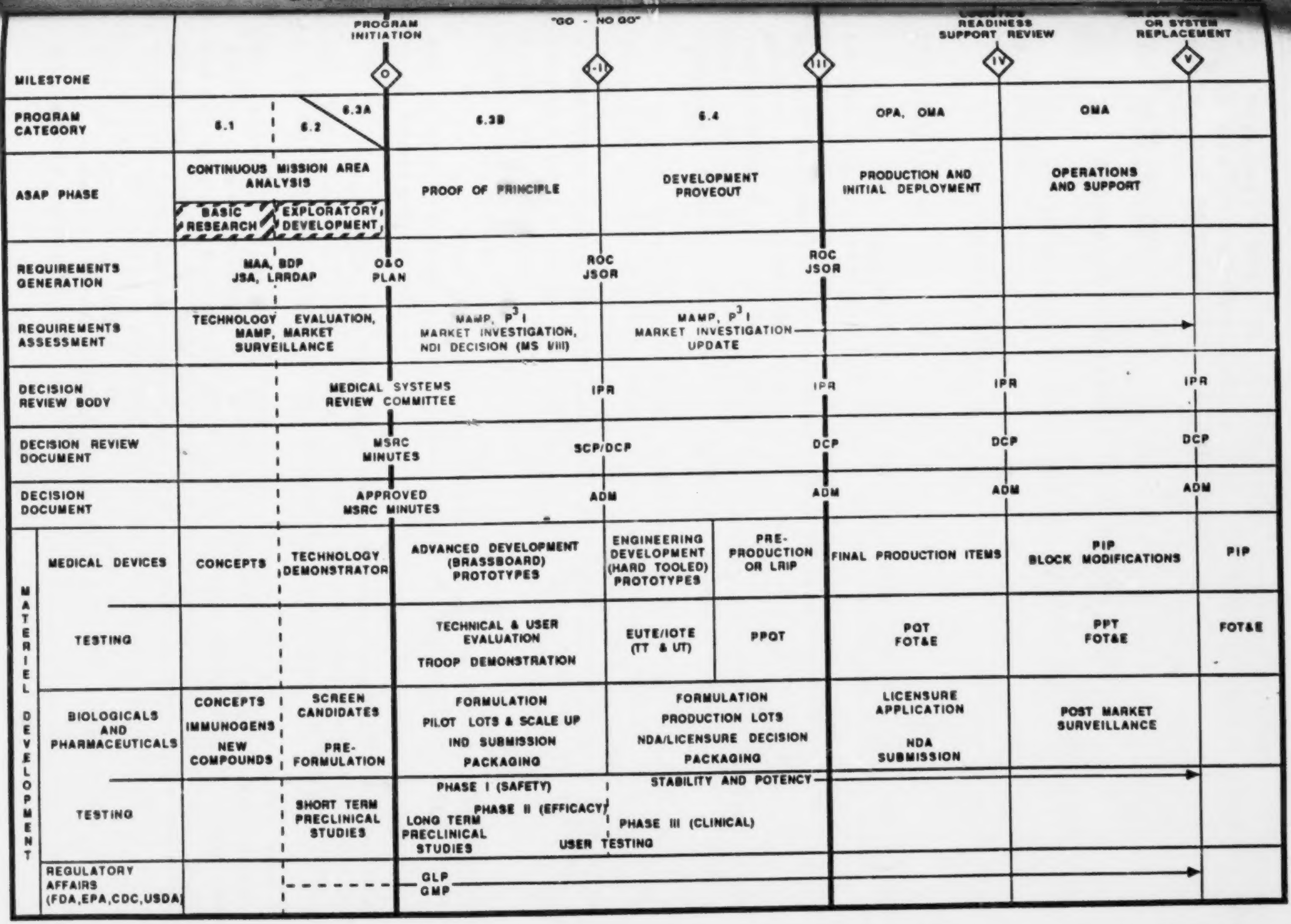
PROPOSER ______________________ REVIEWER ______________________

FACTOR	RAW SCORE (0-4)	X	WEIGHT	=	TOTAL SCORE	COMMENTS
1. Methodology						
a. Understanding of scope of work	______	X	5	=	______	
b. Technical strategy	______	X	10	=	______	
c. Management scheme	______	X	5	=	______	
2. Personnel						
a. Qualifications	______	X	5	=	______	
b. Experience	______	X	5	=	______	
c. Time Apportionment	______	X	5	=	______	
3. Facilities						
a. Analytical chemistry	______	X	5	=	______	
b. Field capability	______	X	4	=	______	
c. Library and info retrieval	______	X	1	=	______	
4. Corporate experience	______	X	5	=	______	
GRAND TOTAL SCORE					______	

STANDARDS FOR SCORING

SCORE	STANDARD
4	EXCELLENT (Substantial response; exceeds all requirements)
3	GOOD (Exceeds minimum requirements only in minor areas)
2	WEAK (Does not meet minimum requirements)
1	INADEQUATE (Fails to respond to requirements in major areas)

PPENDIX E : STREAMLINED MEDICAL MATERIEL ACQUISITION PROGRAM



		6.1	6.2	Milestone 0		Milestone I-II			Milestone III		Milestone IV		Milestone V	
MILESTONE				PROGRAM INITIATION 0		"GO - NO GO" I-II			III		READINESS SUPPORT REVIEW IV		OR SYSTEM REPLACEMENT V	
PROGRAM CATEGORY		6.1	6.2 6.3A		6.3B		6.4			OPA, OMA		OMA		
ASAP PHASE		CONTINUOUS MISSION AREA ANALYSIS BASIC RESEARCH	EXPLORATORY DEVELOPMENT		PROOF OF PRINCIPLE		DEVELOPMENT PROVEOUT			PRODUCTION AND INITIAL DEPLOYMENT		OPERATIONS AND SUPPORT		
REQUIREMENTS GENERATION		MAA, BDP JSA, LRRDAP		O&O PLAN		ROC JSOR			ROC JSOR					
REQUIREMENTS ASSESSMENT		TECHNOLOGY EVALUATION, MAMP, MARKET SURVEILLANCE			MAMP, P^3I MARKET INVESTIGATION, NDI DECISION (MS VIII)		MAMP, P^3I MARKET INVESTIGATION UPDATE →							
DECISION REVIEW BODY				MEDICAL SYSTEMS REVIEW COMMITTEE		IPR			IPR		IPR		IPR	
DECISION REVIEW DOCUMENT				MSRC MINUTES		SCP/DCP			DCP		DCP		DCP	
DECISION DOCUMENT				APPROVED MSRC MINUTES		ADM			ADM		ADM		ADM	
MATERIEL DEVELOPMENT	MEDICAL DEVICES	CONCEPTS	TECHNOLOGY DEMONSTRATOR		ADVANCED DEVELOPMENT (BRASSBOARD) PROTOTYPES		ENGINEERING DEVELOPMENT (HARD TOOLED) PROTOTYPES	PRE-PRODUCTION OR LRIP		FINAL PRODUCTION ITEMS		PIP BLOCK MODIFICATIONS		PIP
	TESTING				TECHNICAL & USER EVALUATION TROOP DEMONSTRATION		EUTE/IOTE (TT & UT)	PPQT		PQT FOT&E		PPT FOT&E		FOT&E
	BIOLOGICALS AND PHARMACEUTICALS	CONCEPTS IMMUNOGENS NEW COMPOUNDS	SCREEN CANDIDATES PRE-FORMULATION		FORMULATION PILOT LOTS & SCALE UP IND SUBMISSION PACKAGING		FORMULATION PRODUCTION LOTS NDA/LICENSURE DECISION PACKAGING			LICENSURE APPLICATION NDA SUBMISSION		POST MARKET SURVEILLANCE		
	TESTING		SHORT TERM PRECLINICAL STUDIES		PHASE I (SAFETY) PHASE II (EFFICACY) LONG TERM PRECLINICAL STUDIES		STABILITY AND POTENCY → PHASE III (CLINICAL) USER TESTING							
	REGULATORY AFFAIRS (FDA,EPA,CDC,USDA)		- - - - - -		GLP GMP →									

LEGEND:

ADM	Acquisition Decision Memorandum
ASAP	Army Streamlined Acquisition Program
BDP	Battlefield Development Plan
CDC	Centers for Disease Control
DCP	Decision Coordinating Paper
EPA	Environmental Protection Agency
EUTE	Early User Test & Evaluation
FDA	Food and Drug Administration
FOT&E	Follow-on Operational Test & Evaluation
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
IND	Investigational New Drug
IOTE	Initial Operational Test & Evaluation
IPR	In-Process Review
JSA	Joint Services Agreement
JSOR	Joint Services Operational Requirement
LCSMM	Life Cycle System Management Model
LRIP	Low Rate Initial Production
LRRDAP	Long-Range Research, Development, and Acquisition Plan
MAA	Mission Area Analysis
MAMP	Mission Area Material Plan
MS	Milestone
MSRC	Medical Systems Review Committee
NDA	New Drug Application
NDI	Non-Developmental Item
O&O	Operational & Organizational
OMA	Operations and Maintenance, Army
OPA	Other Procurement, Army
PIP	Product Improvement Program
PPQT	Pre-Production Qualification Test
PPT	Production Prove-Out Test
PQT	Production QualificationTest
P^3I	Preplanned Product Improvement
ROC	Required Operational Capability
SCP	System Concept Paper
TT	Technical Testing
USDA	U.S. Department of Agriculture
UT	User Testing

pages tightly bound

PPENDIX F : BROAD AGENCY ANNOUNCEMENT (BAA) PROCEDURES

I. **Purpose**: This is to establish uniform policy and procedures, and to assign responsibility for the BAA, proposal receipt and review, and acquisition of research.

II. **References**:

1. Federal Acquisition Regulation (FAR).

2. Congressional letter dated April 15, 1986 to the Secretary of Defense.

3. The USAMRDC BAA.

III. **Policy**:

1. The Competition in Contracting Act (CICA) issued as PL 98-369 authorizes use of "general solicitations" for basic research proposals, and proposal evaluation by use of peer or scientific review. Contracts and grants awarded under these general solicitations meet the "Full and Open" competition requirements of CICA. The FAR 6.102(d)(2), in implementing CICA uses the term "Broad Agency Announcement" (BAA) rather than "general solicitations;" however, the meaning is the same.

2. In consonance with Reference 2, "basic research" is interpreted to include 6.1, 6.2, and 6.3A budget categories. To determine the applicability of the BAA, the primary aim of the research effort, regardless of the funding category, should be to attempt to increase knowledge in science and/or to advance the state of the art. Also, the research effort should meet one of the following criteria:

a. The primary aim should be a better understanding of the subject under study rather than any practical application of that knowledge; or,

b. The primary aim should be to determine and exploit the potential scientific discoveries or improvements in technology, materials, processes, methods, devices, or techniques.

The above is distinguished from efforts whose primary aim is the design, development, or test of specific items or services. The latter are within the definition of "development." The term also does not apply to the purchase of technical or general support services, hardware, construction, or other type non-research effort. Research required to solve a specific operational problem may be procured under the BAA if the primary aim of the project is to do research even though the project result is also used to solve the operational problem.

3. The objective of the BAA process is to recognize that basic research contractor selection is primarily a technical decision with very low business risk. Use of the BAA should also accelerate the acquisition process and save significant labor. The amount of contracting officer involvement, therefore, should be far less than in normal acquisitions. Institutes/laboratories should carefully follow these procedures. The USAMRAA may reject use of the BAA process for specific procurements if, in the contracting officer's opinion, the project does not meet the criteria specified in this procedure. Frequent communication between the institutes/laboratories and USAMRAA will be critical to success of this procedure.

IV. Responsibilities:

1. The Principal Assistant Responsible for Contracting (PARC) shall be responsible for:

a. Establishing uniform policies and procedures for use of the BAA;

b. Publication of the BAA (normally annually);

c. Dissemination of the BAA to prospective contractors;

d. Receipt of preproposals or proposals;

e. Delegating authority to specified institute/laboratory personnel to communicate with prospective contractors;

f. Tracking preproposals and proposals and responses thereto by institutes/laboratories.

2. The Research Area Director (RAD) shall be responsible for screening preproposals or proposals for military relevance. The RAD may decline support of irrelevant proposals at the outset. All other proposals will be forwarded to an appropriate institute/laboratory for further review.

3. The institutes/laboratories shall be responsible for preproposal/proposal review, obtaining required clarifications, declining or technically selecting proposals for support, and documenting that selection or declination.

4. The U.S. Army Medical Research Acquisition Activity (USAMRAA) shall be responsible for announcing the existence of the BAA, selection of the type contract, negotiation of cost/price, and preparation and execution of the contract and related documentation.

5. The Judge Advocate shall promulgate instructions and procedures to prevent conflicts of interest, or the appearance thereof. Required information will be obtained in writing from

reviewers in order to advise the PARC on the propriety of their participation in the evaluation process.

6. Attached is a flow-chart to reflect the BAA process in USAMRDC.

V. Procedures:

1. An announcement of the availability of the BAA will be placed in the Commerce Business Daily at least annually by USAMRAA. In addition, general availability or specific topics included in the BAA may be announced in scientific or technical publications.

2. Reference 3 does not contain closing dates for receipt of proposals; accordingly, proposals may be received on any listed topic at any time. Preproposals are strongly encouraged to preclude offerors from incurring the expense of preparing a complete proposal that my be inappropriate for USAMRDC funding. Complete proposals will be accepted, however, and generally handled in the same manner as preproposals.

3. Preproposals will be initially received by the PARC, and sent within one day to the appropriate RAD(s). The RAD will review the preproposal for military relevance and, if not suitable for USAMRDC support, return it to the PARC for transmission of a turn-down letter to the principal investigator (PI). If the preproposal is militarily relevant, it will be sent to the PARC for transmission to the appropriate institute/laboratory(s). The PARC will track and maintain suspense on all preproposals and proposals via the automated Extramural Research Management System (ERMS).

4. The Acquisition Management Liaison Office (AMLO) in the following institutes/laboratories will be the focal point for BAA preproposals and proposals:

WRAIR
USAMRIID
USABRDL

LAIR (includes ISR)
USAARL
USAMRICD

The Commanders of USARIEM and USAIDR may designate any position desired to manage BAA preproposals and proposals. These positions shall be considered the AMLO for purposes of this procedure. The AMLO will, within 60 days, send a turn-down letter to the PI, or a letter encouraging submission of a complete proposal.

5. If necessary, the Chief, AMLO may communicate directly with the PI to obtain clarification and information on the proposed research. The PARC will delegate, in writing, authority to the Chief, AMLC for the conduct of these preliminary contacts with the PI. This authority may not be redelegated. Care must be taken not to provide detailed information which would give an unfair advantage to one PI over another. In addition, technical

transfusion is prohibited, i.e., disclosing innovative ideas offered by a PI to a competitor. No discussions will take place on cost or price. All points of clarification or modification to the scope of work, method, or approach will be summarized in a letter to the PI. Copies of all letters to the PI will be provided to the PARC and RAD. The PI will submit a complete proposal to the AMLO; the AMLO will send a copy to the PARC for tracking and use by Headquarters. Following receipt of the proposal, no further communication may take place between the Chief, AMLO and the PI. Continued discussion and changes are inappropriate and in violation of the acquisition regulations; the PI is expected to be capable of submitting an acceptable proposal by following the initial suggestions. Any further changes must be submitted to USAMRAA for negotiation between a contracting officer and the prospective contractor's business manager. When specific requirements are known by the AMLO and are not included in the general area described in the preproposal, a Request for Proposal shall be issued. The subsequent procurement will not be effected through the BAA proposal mechanism.

6. In the event a preproposal is sent to more than one institute/laboratory (which will be noted when the preproposal is transmitted from the PARC), no preliminary discussions should take place. Questions, comments, or recommendations should be sent to the PARC, who will coordinate comments from the RADs, and either send a turn-down letter or assign the preproposal to one institute/laboratory for action.

7. Proposals and any modification thereto will normally be incorporated by reference into the contract, and become the Statement of Work. In view of this, the PI must be encouraged to write a clear, precise statement of work, with milestones, as part of the proposal.

8. When complete proposals are submitted rather than preproposals, clarifications and amendments may be obtained under the same procedures employed for preproposals. Confirmation of discussions will be documented. No discussion may take place on cost or price, and no further discussions may take place following submission of the amendment to the proposal. The prohibition against technical transfusion must be strictly adhered to in any communication.

9. The preferred method of review of proposals received under the BAA is scientific review by the USAMRDC contractor responsible for Technology Assessment. However, at the discretion of the institute/laboratory commander, the review may be performed by in-house researchers, consultants, or other Government personnel. In either case, proposals shall be reviewed in accordance with the evaluation factors contained in the BAA. Proposals need not be evaluated against each other, since they are not submitted in accordance with a common work statement. Multiple individual reviewer comments need not be attached to the procurement request.

A written summary is required of the evaluations by:

a. The Technology Assessment contractor; and/or

b. In-house/consultant peer reviewers; and

c. The institute/laboratory commander, e.g., after-action committees.

The written evaluations shall be based on the criterion in the BAA, substantiate the rationale for selection of the proposal, and be in sufficient detail to adequately justify contract award by the contracting officer.

10. Comments on the reasonableness of proposed costs should also be provided. The following categories shall be addressed, as appropriate, including recommendations for change:

a. Personnel: Address the appropriateness of the proposed research staff and level of effort.

b. Capital Equipment: Address the need for each item of major equipment. Where possible, recommend alternatives such as use charge arrangements with other departments, loan of Government equipment, or use of equipment in a USAMRDC laboratory. Specific comments are required on items of equipment costing more than $5,000.

c. Supplies: Comment on the appropriateness of the supply budget.

d. Travel: Discuss reasonableness of proposed travel.

e. Other Direct Costs: Comment on reasonableness.

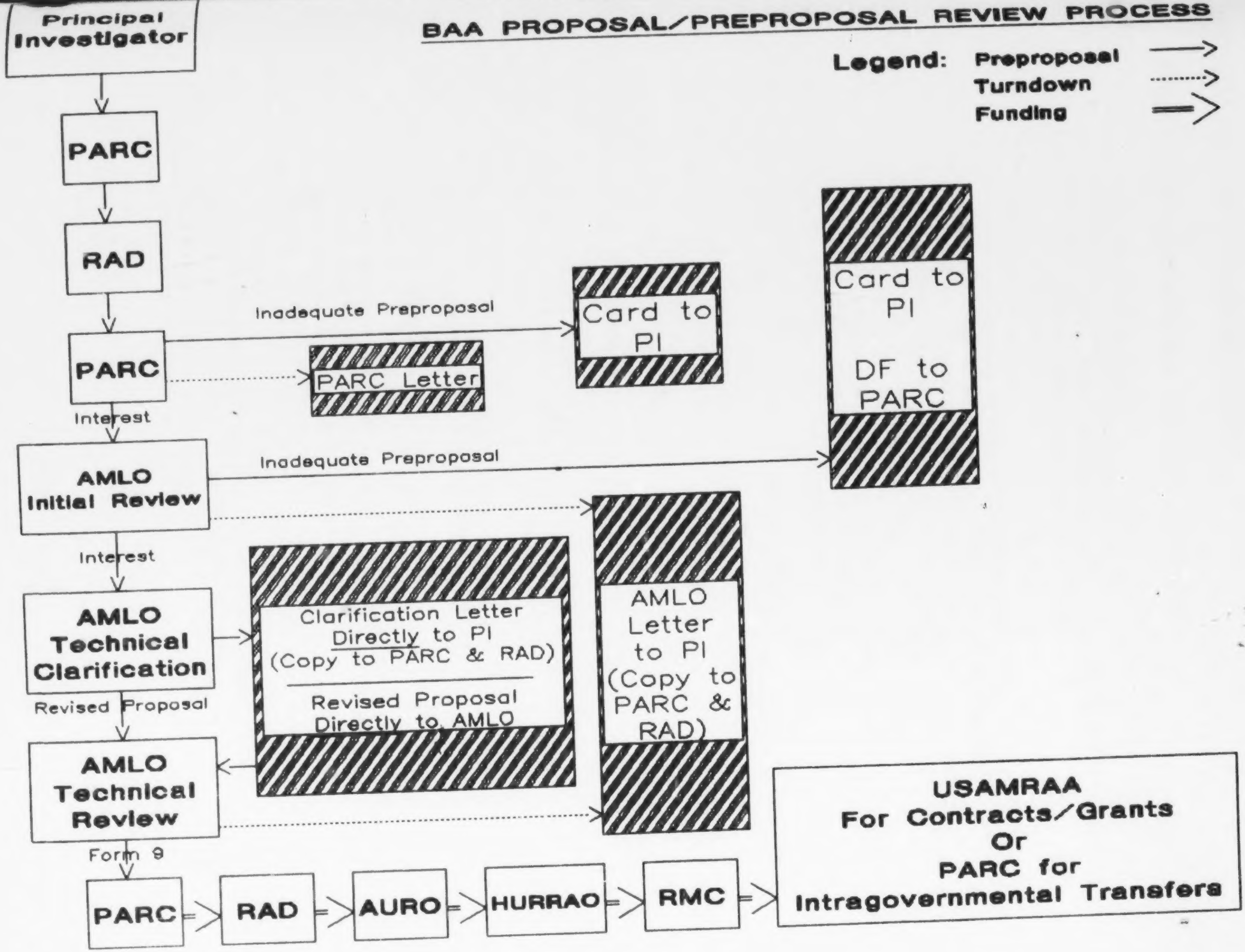
11. Following the decision to support a BAA proposal, the Human Use Review and Regulatory Affairs Office (HURRAO) and Animal Use Review Office (AURO) will review the proposal and obtain necessary clarifications from the PI on issues needing resolution. The HURRAO and AURO are responsible for suspensing and resolving problems. Copies of all correspondence shall be provided to the AMLO and the RAD. The USAMRAA may commence negotiations during HURRAO and AURO reviews; however, contract award will not be made prior to HURRAO/AURO approval.

12. Upon receipt of the procurement request, USAMRAA will determine that contract award has been technically justified, and will evaluate price or costs pursuant to DOD FAR Supplement 35.008. Following negotiations, a Price Negotiation Memorandum will be prepared pursuant to FAR/DOD FAR Supplement 15.808.

13. Cost-reimbursement type contracts will normally be used to support commercial firms. Proposals and any modifications to

the proposals will normally be incorporated by reference into contracts as the Statement of Work. Any changes to the proposal negotiated by the contracting officer will be coordinated with the Chief, AMLO to assure that they properly reflect technical requirements. The USAMRAA will normally award contracts under the BAA process 90 days after receipt of procurement requests which contain the required documentation and approvals.

BAA PROPOSAL/PREPROPOSAL REVIEW PROCESS



PPENDIX G : SOLICITATION OUTLINE

I. ACQUISITION REQUIREMENTS PACKAGE (PO/COR)

___Project background
___SOW/Deliveries/Specifications
___Contract Data Requirements List/Data Item Descriptions
___Gov't Property/Deliveries Logistics
___HUPRAO Coordination
___AURO Coordination
___Hazardous/Surety Materiel Concerns
___Environmental Impact Assessment or Statement
___Management Concerns and Estimates
___Independent Government Cost Estimate
___Desired Content of Technical Proposal
___DD254, Security Requirements
___Proposal Evaluation and Scoring Criteria
___Proposed SSEB Members and DD1555
___Draft CBD/Journal announcements
___Suggested Sources List
___Need for Pre-Proposal Conference
___Projected Funding
___Need for Multiple Awards
___Lab/Institute Commander Approval
___RAD Approval
___Other issues addressed as necessary

II. SOLICITATION MILESTONES (CO)

___Receipt of Acquisition Requirements Package
___Small Business Determination, DD Form 1877
___CBD Synopsis Publicizing Acquisition
___Synopsis Responder List
___Request for Proposal (RFP) Released
___Preproposal Conference, as necessary
___Proposals Received
___SSEB Members Approved/Certified
___Technical Evaluation of Proposals
___SSEB Meeting/Evaluation/Find Competitive Range
___SSEB Meeting/Best and Finals Evaluation/Final Issues
___Pre-Award Survey/Site Visits
___Audit Reports Received
___Pre Business Clearance Memorandum Approved
___Negotiation Completed
___Post Business Clearance Memorandum Approved
___Contract Document Prepared/Approved
___Contract Signed By Contractor, then CO
___Contract Awarded

PPENDIX H : CONTRACTING FOR DEVELOPMENT

A. DEFINITIONS

Development means the systematic use of scientific and technical knowledge in the design, development, testing, or evaluation of a potential new product or service (or of an improvement in an existing product or service) to meet specific performance requirements or objectives. It includes the functions of design engineering, prototyping and engineering testing. (FAR 35.001)

Advanced Development means all effort directed toward projects which have moved into the development of hardware for test. The prime result of this type of effort is proof of design concept rather than the development of hardware for service use. Projects in this category have a potential military application. (DFAR 235.001)

Engineering Development means those projects in full-scale engineering development for service use but which have not yet received approval for production or had production funds included in the DoD budget submission for the budget or subsequent fiscal year. This area is characterized by major line item projects and program control will be exercised by review of individual projects. (DFAR 235.001)

Exploratory Development means all effort directed toward the solution of specific military problems, short of major development projects. This type of effort may vary from fairly fundamental applied research to quite sophisticated bread-board hardware, study, programming and planning efforts. It would thus include studies, investigations and planning effort. The dominant characteristic of this category of effort is that it be pointed toward specific military problem areas with a view toward developing and evaluating the feasibility and practicability of proposed solutions and determining their parameters. (DFAR 235.001)

B. ACQUISITION ISSUES

In preparing a development-type procurement package, the program officer should address the following topics:

1. Performance specifications or functional purchase description.

a. Performance specifications set forth operational characteristics desired for the item. In such specifications, design, measurement, and other details are not stated or considered important if the performance requirement is met. The contractor accepts responsibility for design, engineering, and the achievement of the stated performance characteristics. The Government reserves the right of final inspection and acceptance.

b. Design specifications set forth precise measurements, tolerances, materials, tests, quality control, inspection requirements, and other specific information. Under this type of specification the Government is responsible for the design and also responsible for omissions, errors, and discrepancies in the specifications and drawings.

2. Technical data required.

3. Type of testing to be done.

4. Type of quality assurance required.

5. Such Required or desired delivery issues as:

a. Technical data and computer software requirements. The Government only acquires rights in technical data or computer software that is called for delivery under the contract, and that delivery is governed by the Contract Data Requirements List (DD 1423) of the contract. The SOW, even if it includes a requirement for the development or generation of technical data, will not generally create an obligation on the contractor to deliver those data items unless they have been identified on the DD 1423. Technical data and computer software are becoming the subject of increasing emphasis in DOD. There are three types of rights which apply to technical data and computer software delivered under Government contracts --

(1) Unlimited. Unlimited rights allow the Government to use, duplicate or disclose technical data or computer software in any manner and for any purpose, including its use in competitive reprocurement.

(2) Limited Rights. Limited rights prohibit the right to use, duplicate or disclose technical data without permission of the party furnishing the data, except for emergency repairs or release to foreign governments under certain circumstances.

(3) Restricted Rights. Restricted rights apply only to computer software and are subject to restrictions imposed by the party furnishing the software. These restrictions can be negotiated; however, the Government does acquire, as a minimum, the right to --

o Use computer software with the computer for which it was acquired.

o Use computer software with a backup computer.

o Copy computer programs for safekeeping.

o Modify computer software, or combine it with other software, provided that the derivative software is also subject to the same restricted rights.

(4) Commercial Computer Software is software used regularly for other than Government purposes and which is sold, licensed or leased in significant quantities to the general public at market or catalog prices. The Government has the right to buy or lease,just as any other company does.

b. Contract security classification specification. If the requirement involves the generation of classified information, material, or areas or access will be required during the performance of the contract, a DD Form 254 (Contract Security Classification Specification), must be a part of the procurement package. Appendix I of the Industrial Security Manual sets forth guidance on the preparation of the form.

c. Automatic data processing equipment (ADPE). ADPE approvals generally fall into two categories, approval of the requirement (AR 25-5) which must be submitted with the procurement package, and the delegation of procurement authority. The topic of ADPE approvals is complex, ever-changing, and rife with exceptions and variations; upon first identification of a need for ADPE, contact your Information Management Division for wise words.

6. Independent Government cost estimates (IGCE). An IGCE must be provided with every procurement package. The complexity of the estimating technique shall be commensurate with the complexity of the acquisition. A greater detail of cost breakdown is required for negotiated procurements than formal advertising.

7. Test, measurement and diagnostic equipment (TMDE). AR 750-43 governs TMDE. Prior to submitting a requirement for TMDE, approval must be obtained from the Central DA TMDE Activity, US Army Maintenance Management Center, Lexington, KY, and made a part of the procurement package. If the requested item does not fall under AR 750-43, a statement must be include in the Instructions for Contracting Officers (see below) that the requirement is not TMDE and as such does not require the approval of the Central DA TMDE Activity.

C. SOLE SOURCE JUSTIFICATION

10 USC 2304(g) requires that all Government contracts be solicited from the maximum number of qualified sources consistent with the nature of the supplies and services to be procured. A sole source determination is in essence a certification of current knowledge by the signer(s) that only one firm can perform the required work. GAO Report PLRD-81-45 admonishes contracting officers to question the validity of sole source statements and market surveys made by technical advisors. The justification must contain factual details supporting the conclusion, not self-serving conclusionary statements.

1. Factors. A contract may be awarded on a sole source basis because of several factors which individually would not be persuasive but collectively leave the Government with no alternative;

a. Time Urgency. Competition may be legitimately restricted to a single source of supply where it can be clearly shown that only one firm can deliver or perform within the required time frame. The justification must provide factual details clearly establishing that the deadline is both necessary and genuine; the adverse consequences if the deadline is not met must be expressly outlined. Time alone is not usually sufficient, particularly for requirements which could have been predicted with a reasonable degree of certainty.

b. Unique Capability. If a particular contractor legitimately has a truly unique product or capability that is genuinely needed by the Government, then a sole source award would be proper; e.g., proprietary data or patent. This product must not exceed the Government's minimum need.

c. Compatibility. The Government may restrict competition to one source for legitimate compatibility or interchangeability purposes. This is more difficult in ADPE due to the interface capability or software conversion; the interface or conversion may be a cost evaluation factor in determining the lowest total overall cost to the Government; the marketplace is the determinant.

d. Unavailability of Data. Generally a sole source procurement is appropriate when the Government does not have adequate specifications and drawings necessary for a competitive procurement; if the data is being developed for the Government, then the sole source justification must also explain why the procurement action cannot wait until that data becomes available.

e. Innovative Unsolicited Proposals. Genuinely innovative unsolicited proposals receive qualified preferential treatment in the FAR. The sole source award of an unsolicited proposal is appropriate when only one source can do the job; the unsolicited proposal offers significant scientific or technological promise, represents the product of original thinking and was submitted in confidence by one source; or award will take advantage of unique and significant industrial accomplishment or insure that a new product or idea is given financial support.

2. Nonfactors. It is improper to base a sole source justification on the following:

a. Preference for Superior Quality. The Government is only permitted to purchase supplies or services that meet its minimum needs.

b. Speculation as to Winner. Speculation is an improper substitute for the true test of competition; i.e., belief that the prospective awardee has such a competitive advantage that it would win the competition because of the advance knowledge.

c. Cost Savings. Sole source would be less expensive for the Government; cost reduction considerations are generally enhanced by increased competition.

d. Opinions. Unsupported self-serving opinions and conclusions are not persuasive and should always be accompanied by supporting evidence.

e. Duplication of Work. The sole fact that some minor duplication of earlier efforts would be required is inadequate.

3. Documentation. The sole source justification must be prepared by the requesting activity and be a part of the procurement package and contain the following information at a minimum:

a. The installation or activity requesting sole source approval.

b. Name and address of the company the Government proposes to contract with.

c. A description of the requirement.

d. Estimated quantities or level of effort, to include option quantities.

e. When delivery is required or the period of performance.

f. Specific and detailed justification as to why items can be procured from only one source.

g. Previous procurement history.

h. Impact if sole source justification is not approved.

i. Specify actions taken or being taken to insure that follow-on procurements will be competitive.

j. Certification as to factual accuracy by the requestor.

D. INSTRUCTIONS FOR CONTRACTING OFFICERS

Every procurement package, other than for routine off-the-shelf items, must contain Instructions for Contracting Officers.

1. Delivery Schedules. Delivery schedules are an essential part of every contract and must be realistic from the point of both attainability and responsiveness to the Government's needs.

Consideration must be given to such factors as procurement leadtime, manufacturing time, and the urgency of the requirement. A compressed schedule may increase both the cost and risk and should be avoided if at all possible.

2. Place of Delivery or Performance. The "ship to" address as well as "Mark for" instructions must be provided for supply items. For services, the place(s) of performance must be specified.

3. Packaging and Packing. When the requirement is for supply items, the level of packaging and packing must be specified; commercial pack or military standards and at what level.

4. Quality Control. The contractor is responsible for establishing manufacturing quality and inspection controls to ensure that supplies and services delivered to the Government conform to contract requirements. The level of quality control must be specified; e.g., MIL-I-45208, Inspection System Requirement or MI-Q-9858, Quality Program Requirement.

5. Inspection and Acceptance. The place of inspection and acceptance, origin or destination must be specified.

a. Preliminary inspection at origin; final inspection and acceptance at destination. Preliminary inspection will consist of a review of those factors specified by the technical activity and will be conducted by the DCAS QA representative when performance is at the contractor's facility. Final inspection and acceptance will be accomplished at destination by the technical activity normally within 30 days of receipt unless some other time frame for acceptance is spelled out in the contract. The technical activity cannot inspect and accept at the contractor's facility unless a specific waiver is obtained by the contracting officer.

b. Final inspection at origin; acceptance at destination. The DCAS QA representative will, on behalf of the Government, conduct all inspection procedures for supplies or services delivered; the items will be accepted at destination by the technical activity.

c. Final inspection and acceptance at origin. DCAS QA will perform both the inspection and acceptance. Destination functions are limited to a visual inspection to determine if there is any freight damage for issuance of a claim against the carrier.

d. Final inspection and acceptance at destination. The technical activity will perform both the inspection and acceptance at destination; DCAS QA functions will normally be limited to in-process surveillance requested by the contracting officer.

6. Foreign End Product. If the requirement is an item that consists of more than 50 percent foreign produced components in monetary terms rather than quantity, a determination must be

provided that the item is exempt from the Buy American Act, or that a suitable domestic item is not available.

7. Government Furnished Property. Items to be provided to the successful contractor as Government Furnished Property (GFP) for performance of the contract effort must be specifically identified. A complete list of all GFP to include the following information must be provided:

a. The items to be provided.

b. The dollar value of each item.

c. If the GFP is accountable under an existing contract, the contract number, contractor and the property administrator.

d. A positive delivery date of the GFP to the successor contractor; a certification that the GFP will be available on the date specified. If specific date is not possible, specify the date in number of days after award or number of days prior to performance.

e. The condition of each item.

f. Name and telephone number of the point of contact.

8. Hazardous Material Identification and Safety Data. Identify when hazardous materials will be delivered or if there will be an exposure to hazardous materials in any manner; e.g., performance of work, use, handling, transportation, inspection or disposal; if none, state so. The list of hazardous materials is found in Appendix A of Federal Standard No. 313A.

9. Options. Option items may be requested when there is reasonable certainty that funds will be available, competition for the item is impractical once the initial contract is awarded and it is not readily available on the open market. When a supply contract, option quantities must be specified; when a service, the option is expressed in time.

E. CONTRACT TYPES

1. Firm Fixed-price. (FFP) Completion.

a. **Characteristics.** Calls for delivery of supplies or services at a specified firm price fixed at inception of the contract and not subject to adjustment in light of actual cost of performance.

b. **Application.**

(1) When fair and reasonable pricing can be established at the outset.

(2) Availability of reasonably definite specifications.

(3) Experienced and adequately competitive market.

(4) Purchase of "off-the-shelf" items, modified commercial items and military items for which sound prices can be developed.

(5) Where performance uncertainties can be identified and reasonably estimated as cost variants, and the contractor agrees to a FFP at a level which entails a reasonable sharing of risk.

c. **Advantages.**

(1) Easiest and least costly type contract to administer.

(2) Encourages contractor efficiency and economy.

(3) Maximum risk for profit or loss borne by contractor.

(4) Allows accurate obligation of funds at outset.

d. **Disadvantages.**

(1) No recovery by Government if market prices fall.

(2) Lacks flexibility.

e. **Limitations.** None

f. **Remarks.** Since a fixed price contract should specify exactly what the contractor is required to do for a specific price, any change or variation in the requirement must be done by formal modification to the contract. This can result in innumerable modifications. Modifications to existing fixed price contracts can be costly as it puts the Government in a position of negotiating the work on a sole source basis. In addition, any change in scope or defined uncertainty which is outside the scope of a fixed price contract is considered new work and requires a new contract.

2. Fixed-price incentive (FPI)

a. **Characteristics.** Applies profit motivation to obtain more economy and efficiency in defense procurement by offering proportionately high profit for outstanding, effective and economical contract performance; modest profit for mediocre performance and low profit or loss for below average economy and efficiency in contract performance.

b. **Application.** When the use of FFP will not provide the needed incentive to motivate the contractor to fulfill the Government's needs (time, cost or performance).

c. **Limitations.**

(1) Requires a determination and findings supporting the use of incentive provisions; the contracting officer has the responsibility for its preparation.

(2) Contractor's accounting system just be adequate for price revision purposes and allow satisfactory application of price adjustment formula.

(3) Not appropriate for shifting substantially all cost responsibility to the Government.

d. **Remarks.**

(1) Under appropriate individual contract circumstances, performance and delivery incentive provisions may be added to cost incentive. Incentive provisions must be kept in balance as concerns the needs and best interests of the Government.

(2) Objective is to obtain what is needed, when it is needed for the requirement at the lowest cost to the Government by the most practical means; is not designed to replace FFP.

(3) Billing price is established at the outset as interim basis of payment pending determination of final incentive fee earned.

(4) Effect of delays and additional costs caused by the Government and beyond control of the contractor will normally be treated outside the incentive pattern or be subject to equitable adjustment.

3. Firm fixed-price level of effort (TERM).

a. **Characteristics.**

(1) Describes the scope of work in general terms, usually calling for study or services.

(2) Normally requires the contractor to submit reports which show the results achieved through application of required level of effort.

(3) Payment is based on time expended rather than on results achieved.

b. **Application.** Particularly useful in the research and development area, studies, or technical services when the work cannot be clearly defined; the level of effort desired can be identified and agreed upon in advance.

c. **Advantages.** Can be used in situations in which an administratively expensive cost reimbursement contract might otherwise be necessary.

d. **Disadvantages.** Does not guarantee that desired results will be achieved.

e. **Limitations.**

(1) Can be used only when the work to be performed cannot otherwise be clearly defined.

(2) Level of effort desired must be identified and agreed upon in advance of performance.

(3) There must be reasonable assurance that the result desired cannot be achieved by expenditure of less than the stipulated effort.

f. **Remarks.** None.

4. Cost-plus-incentive-fee. (With incentive on cost)

a. **Characteristics.**

(1) Provides a target cost, a target fee, a minimum and maximum fee, and a fee adjustment formula, all established during negotiations before award.

(2) Upon contract completion, the formula is applied and, subject to the minimum and maximum fee limits, the fee is adjusted by either an increase from target for total allowable cost underrun or a decrease from target for allowable cost overrun.

(3) May be multiple incentive with an incentive on delivery or performance in addition to cost.

b. **Application.**

(1) A given level of performance is desired and confidence in achieving that performance level is reasonable good, but technical and cost uncertainties are excessive for a FPI contract.

(2) When the performance is measurable, an incentive formula can be negotiated which will provide positive incentive for the contractor to perform based upon the Government's needs.

c. **Advantages.** Encourages economical, efficient and effective contractor performance when a cost reimbursement type contract is necessary.

d. **Disadvantages.** Costly auditing and administration.

e. Limitations.

(1) A high maximum fee should be balanced by a low minimum fee, which may even be a "zero."

(2) Requires a determination and findings signed by the contracting officer supporting the selection on the basis of economy or practicality.

(3) The contractor must have an approved accounting system.

f. Remarks.

(1) The minimum fee should be set for reasonable foreseeable variation above target cost; maximum fee at lowest reasonable foreseeable cost.

(2) Delays and costs beyond the control of the contractor will normally be treated outside the incentive pattern or be subject to equitable adjustment.

5. Additional Incentives (performance or delivery).

a. **Characteristics.** Provides an incentive to the contractor to surpass performance targets by increasing or decreasing profits in relation to surpassing or failing to meet performance targets.

b. **Application.** Is appropriate for use when performance and/or delivery is critical to fulfill the mission needs.

c. **Advantages.** Can foster efficiency and effectiveness by the contractor to mutual benefit of both the contractor by increased profits and the Government by meeting its need.

d. **Disadvantages.** Costly to administer and may be difficult to evaluate performance to include equating the effect of change orders.

e. **Limitations.** Performance or delivery incentive must always be coupled with a balancing cost incentive.

f. **Remarks.**

(1) The Government should specify the minimum requirements which will be mandatory under the contract.

(2) Criteria for evaluating the performance must be measurable.

(3) The contract must establish the effect of changes/modifications on the incentive fee arrangement.

6. Cost-plus-award-fee (CPAF).

a. **Characteristics.**

(1) Comparable to CPIF except the evaluation for fee purposes is subjective and not measurable.

(2) The contract provides for a base fee, not to exceed 3 percent, which is fixed and will be received regardless of quality of performance; an award fee not to exceed 7 percent, will be earned based on quality of performance. The award fee may exceed 7 percent if the base fee is less than 3 percent. The base fee is limited to 3 percent and total fee to 10 percent.

(3) Quality of the contractor's performance is usually evaluated quarterly by the Government with written reports furnished the contractor calling attention to both meritorious work and deficiencies, offering opportunity for corrective action to improve subsequent evaluations. The evaluation determines the amount of award fee received; the contractor cannot recoup lost fee in subsequent evaluations.

(4) The award fee determination is unilateral by the award fee determining official and not subject to appeal under the 'disputes' clause.

b. **Application.**

(1) Appropriate for use when contractor's performance is essential but the measurement of achievement is subjective rather than objective.

(2) The most common use is in service contracts.

c. **Advantages.** Offers more incentive for contractor efficiency and economy than a CPFF contract.

d. **Disadvantages.** Expensive to administer; evaluation of performance requires a significant effort.

e. **Limitations.**

(1) Requires a Determination and Findings by the contracting officer supporting the use.

(2) Shall not be used where the contract amount, period of performance or the benefits expected are insufficient to warrant the additional administrative effort or cost.

f. **Remarks.** Timeliness of rendering periodic evaluation reports is critical to proper operation of this contract. In addition, maximum administrative effort should be made to provide consistent evaluation standards.

7. Time and materials.

a. Characteristics.

(1) Provides for payment of direct labor hours at specified fixed hourly rates (including direct and indirect labor, overhead, general and administrative expense and profit), and material.

(2) Requires a price ceiling which the contractor may not exceed except at own risk; the contracting officer must document the contract file substantiating any change to the price ceiling and modify the contract.

b. **Application.**

(1) Normally used for repair and return or engineering services.

(2) Used when the nature of work is known in advance, but not the extent or duration.

c. **Advantages.** Can fulfill a special situation need that no other type of contract can suitably serve.

d. **Disadvantages.**

(1) Danger of the contractor running up time to increase profit.

(2) Expensive to administer.

(3) No positive profit incentive for the contractor to control costs or to manage the labor force efficiently.

e. **Limitations.**

(1) Requires a determination and findings by the CO as to why no other type of contract will fulfill the requirement.

(2) Contractor needs an adequate accounting system.

(3) Currently the use of a time and materials contract requires higher headquarters approval.

f. **Remarks.** The use is greatly discouraged.

8. Labor hour. All features of a labor hour contract are the same as a time and materials contract except only time is involved, no materials.

APPENDIX I: PROCEDURES FOR AVOIDING CONFLICT OF INTEREST

I. Purpose: This is to establish uniform procedures regarding post-employment participation of USAMRDC personnel in the extramural program.

II. Reference: Army Regulation 600-50 Standards of Conduct for Department of the Army Personnel, as amended.

III. Procedures: The referenced regulation shall be followed by all USAMRDC personnel to avoid conflicts of interest and avoid the appearance of conflicts of interest. No former military member or employee of USAMRDC can represent himself or any organization if the former member or employee personally and substantially participated in the decision process to implement a project to be performed by grant or contract. "Represents" means to act for himself or be the agent authorized to enter into or to administer a contract on behalf of an organization. The individual may be reimbursed under a contract or grant with USAMRDC, and he or she may participate in a technical or scientific capacity in the research. The USAMRDC Reservist Individual Mobilization Augmentees (IMA) may perform research and be reimbursed under a USAMRDC contract. An IMA may not, however, participate at any time in an extramural research program review or approval process should they be performing research under a USAMRDC contract or grant, whether or not salary is paid under the contract/grant. No military member, employee, consultant or advisor participating in review or making recommendation concerning the USAMRDC extramural research program may perform research on a USAMRDC contract or grant, whether or not his salary is paid under the contract/grant. Government employees cannot be a principal investigator for performance of a research contract or grant without the approval of the other Government agency and written evidence of this approval is provided to the USAMRDC contracting officer.

PPENDIX J :

SITE VISIT CHECKLIST

Contract No.__________________ Date of visit ____________________

Contractor __________________ PI ______________________________

Attendees/Position:

Contractor	USAMRDC

ITEM	NOTES

Background Information Needed

___ Contract with SOW

___ Latest approved budget

___ Changes pending

___ Most recent progress reports

___ Last site visit report

___ Recent correspondence

Personnel

___ PI time on project appropriate?

___ PI associates capable/interested?

___ Budgeted personnel actually on the job?

___ Number of personnel appropriate to job?

___ Human subject standards being met?

Facilities

___ Is project lab space adequate?

___ Normal lab safety observed?

___ All required equipment on hand?

___ Animal facilities adequate/clean?

___ Animal use seems as approved?

___ CSSO requirements being met?

Science

___ Is work addressing the SOW?

___ Is work on schedule?

___ Changes in hypothesis needed?

___ Changes in protocol needed?

___ Are data recorded properly?

___ Are results valid?

___ Are interpretations valid?

___ PI plans for next year(s)?

___ Patentable innovations possible?

Miscellaneous

___ PI understands contract/SOW provisions?

___ PI understands reporting requirements?

___ PI understands change procedures?

___ Any problems or delays?

Additional Comments/Notes

APPENDIX K: PROGRESS / PERFORMANCE REPORTS

Overview: Requirements and format standards which meet basic USAMRDC and DOD research project report needs are incorporated in the standard USAMRDC research contract Section F, shown below. Variations on this standard are permissible in order to meet specific program needs. Accordingly, the COR should read the Section F of the actual contract he is monitoring.

SECTION F: DELIVERIES OR PERFORMANCE

F.1 REPORTS - GENERAL

a. Complete, accurate and timely reports on the progress and findings of the research supported by this contract are required. Failure to meet prescribed standards of either quality or timeliness of the reports may be cause for termination of the contract, delays in the release of periodic funding, and withholding of payments as prescribed by Department of Defense Supplement 52.227-34 of the Federal Acquisition Regulations.

b. The contractor will submit the following technical reports:

(1) Quarterly Reports

(2) Midterm Report

(3) Final Report

(4) Copies of manuscripts submitted for publication

(5) Copies of abstracts for professional meetings

(6) Reprints of publications when available

(7) News releases related to this contract

F.2 QUARTERLY REPORTS

a. Quarterly reports are the most immediate and direct contact between the Principal Investigator (PI) and the Contracting Officer's Representative (COR). The reports provide the means for keeping this Command advised of developments and problems as the contract effort proceeds. The Quarterly reports also provide a measure against which decisions on release of funding and on requests for supplements are made.

QUARTERLY REPORT

1. Contract No.________________ 2. Report Date________________

3. Reporting period from ________________ to ________________

4. PI__________________________ 5. Telephone No.____________

6. Institution ____

7. Project Title:____

____

8. Current staff, with percent effort of each on project.

__________________________ ______________________________

__________________________ ______________________________

__________________________ ______________________________

9. Approximate PI contract expenditures to date;

Personnel_________________ Supplies______________________

Travel _________________ Other_________________________

Equipment over $5000 ______________________________________

10. Comments on administrative and logistical matters.

11. Use the reverse side and additional pages, as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

12. Use the reverse side to present a brief statement of plans or milestones for the next quarter.

b. A Quarterly report shall be submitted for each three month period beginning with the effective date of the contract. This requirement includes the three month periods preceding both the Midterm and Final reports described in Sections F.3 and F.4, respectively.

c. Photocopies of the blank Quarterly report sample shown on the preceding page will serve as the format. Each item of the report format will be completed or addressed.

d. Copies of the report shall be submitted to the addresses shown below within 15 days after the end of each quarter. Internal Government distribution will be made by those offices.

(1) Four copies of the report to: (AMLO)

(2) One copy of the report to: (USAMRAA)

F.3 MIDTERM REPORT

a. A MIDTERM REPORT shall be prepared to provide a complete summary of the research activity for the first half of this contract effort.

b. The MIDTERM REPORT will be prepared so as to meet the same technical standards as manuscripts approved for publication by refereed scientific journals. See Item F.5, "Format Requirements for Midterm and Final Reports," for additional instructions.

c. The MIDTERM REPORT will be prepared specifically for this requirement. Quarterly or other interim reports, or journal articles may not be used in toto as any part of the report.

d. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Statistical tests of significance shall be applied whenever they are appropriate. Extensive tabulation, printouts, or other data that would be awkward to present in the text should be incorporated into the appendix.

e. All experimental methods used during the report period will be referenced to formal publications or presented in enough detail that another investigator familiar with the area can repeat the experiments from the report.

f. The report will include coverage of significant negative results or findings. Such information is invaluable to USAMRDC program planners.

g. Six (6) copies of the report shall be sent within thirty (30) days of the calendar midpoint of the contract to:

Commander
US Army Medical Research and Development Command
ATTN: SGRD-RMI-S
Fort Detrick
Frederick, MD 21701-5012

h. Reports will be reviewed for scientific content, address to the contract Statement of Work, and conformity to the reporting requirements stated in this Section and Section F.5. Unacceptable reports will be returned to the principal investigator for necessary corrections, re-typing and re-submission.

i. The importance of the MIDTERM REPORT to decisions relating to continued support of the contract cannot be overemphasized.

F.4 FINAL REPORT

a. A FINAL REPORT covering the entire term of the contract shall be submitted. The report shall be a complete summary of the research findings after the midterm of the contract. In addition, the report will summarize the entire contract effort, citing data in the MIDTERM and this FINAL report, as necessary.

b. The FINAL REPORT will be prepared so as to meet the same technical standards as manuscripts approved for publication by refereed scientific journals. See Item F.5, "Format Requirements for Midterm and Final Reports," for additional instructions.

c. The FINAL REPORT will be prepared specifically for this requirement. Quarterly or other interim reports, or journal articles may not be used in toto as any part of the report.

d. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Statistical tests of significance shall be applied whenever they are appropriate. Extensive tabulation, printouts, or other data that would be awkward to present in the text should be incorporated into the appendix.

e. All experimental methods used during the report period will be referenced to formal publications or presented in enough detail that another investigator familiar with the area can repeat the experiments from the report.

f. The report will include coverage of significant negative results or findings. Such information is invaluable to USAMRDC program planners.

g. Six (6) copies of the report shall be sent within thirty (30) days of the end of the contract term to:

Commander
US Army Medical Research and Development Command
ATTN: SGRD-RMI-S
Fort Detrick
Frederick, MD 21701-5012

h. Reports will be reviewed for scientific content, address to the contract Statement of Work, and conformity to the reporting requirements stated in this Section and Section F.5. Unacceptable reports will be returned to the principal investigator for necessary corrections, re-typing and re-submission.

i. The FINAL REPORT must be accompanied by a document showing a bibliography of all publications and meeting abstracts, a list of all personnel receiving pay, and the graduate degrees resulting from the contract support.

j. The relationship of report quality and timeliness to the release of the balance of contract funds cannot be overemphasized.

F.5 FORMAT REQUIREMENTS FOR MIDTERM AND FINAL REPORTS

a. All Midterm and Final Reports shall have the following elements:

(1) FRONT COVER: As described in Item 5b, below.

(2) DD Form 1473 - Report Documentation Page: As described in Item 5c, below.

(3) FOREWORD - As described in Item 5d, below.

(4) TABLE OF CONTENTS: Typed on a separate page.

(5) INTRODUCTION: Narrative which describes the nature of the problem, the background of previous work, the purpose of the present work, and the methods of approach.

(6) BODY: Narrative which describes the experimental methods used and the results obtained, and discusses these relative to the goals of the research.

(7) CONCLUSIONS: Summarizes the implications of the completed research and, where possible, recommends changes or future work to better address the problem topic.

(8) REFERENCES:

(9) APPENDIX: As necessary to present additional data, etc.

b. FRONT COVER:

(1) Utilize a photocopy of the blank Front Cover shown at the end of this Section F, Deliveries.

(2) Type in the information to complete the first six items, Contract Number through Type of Report.

c. DD Form 1473 - REPORT DOCUMENTATION PAGE:

(1) Utilize a photocopy of the DD Form 1473 shown at the end of this Section F, Deliveries.

(2) Type in appropriate entries for Items 6a, 6b, 6c, 11, 12, 13a, 13b(Use contract anniversary dates), 14, 15, 18 and 19. The Abstract in item 19 should tell what was done; how it was done; what were the principal results and their significance, in approximately 100-200 words.

d. FOREWORD

(1) Utilize a photocopy of the FOREWORD page shown at the end of this Section F, Deliveries.

(2) Initial the statements which apply to the report.

(3) Sign and date the FOREWORD page. Insert the page after the DD Form 1473.

e. All report materials will be typed or drawn as black on white paper. The clarity of the type and any figures must allow for good reproduction as Microfiche. Word processing output must be letter quality or better.

f. Figures and Tables will be constructed and labelled according to the same standards and specifications required by refereed scientific journals.

F.6 Manuscripts for Publication

a. Contractors are encouraged to publish results of research supported by USAMRDC in appropriate publications. Any publication which may create a statutory bar to the issuance of a patent on any subject invention shall be coordinated with appropriate counsel.

b. Manuscripts intended for publication in any media shall be submitted to Commander, US Army Medical Research and Development Command, Attn: SGRD-RMI-S, Ft. Detrick, Frederick, MD 21701-5012, simultaneously with submission for publication.

Review of such manuscripts is only for comment to the Principal Investigator, not for approval or disapproval.

c. Reports and Abstracts which appear in professional journals and programs shall include the following statements:

(1) "This work was supported by the US Army Medical Research and Development Command under Contract No. DAMD17-______________________."

(2) "Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army."

(3) "In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

(4) "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by 45 CFR 46 (Protection of Human Subjects)."

d. Four copies of all publications resulting from the sponsored research shall be forwarded to the address shown in F.6b, above. Copies shall be forwarded even though publication may in fact be subsequent to the expiration of the contract.

F.7 Public Releases

The contractor shall coordinate and discuss with the Contracting Officer's Representative (COR) all publications, news releases, abstracts for meetings, etc., prior to release to the public.

SSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

SECURITY CLASSIFICATION	1b. RESTRICTIVE MARKINGS
TY CLASSIFICATION AUTHORITY	3. DISTRIBUTION / AVAILABILITY OF REPORT
SSIFICATION / DOWNGRADING SCHEDULE	
MING ORGANIZATION REPORT NUMBER(S)	5. MONITORING ORGANIZATION REPORT NUMBER(S)

OF PERFORMING ORGANIZATION	6b. OFFICE SYMBOL (*If applicable*)	7a. NAME OF MONITORING ORGANIZATION
SS (*City, State, and ZIP Code*)		7b. ADDRESS (*City, State, and ZIP Code*)
OF FUNDING / SPONSORING NIZATION	8b. OFFICE SYMBOL (*If applicable*)	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER

SS (*City, State, and ZIP Code*)	10. SOURCE OF FUNDING NUMBERS			
	PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO.	WORK UNIT ACCESSION NO.

(*Include Security Classification*)

ONAL AUTHOR(S)

OF REPORT	13b. TIME COVERED FROM ________ TO ______	14. DATE OF REPORT (*Year, Month, Day*)	15. PAGE COUNT

LEMENTARY NOTATION

COSATI CODES			18. SUBJECT TERMS (*Continue on reverse if necessary and identify by block number*)
D	GROUP	SUB-GROUP	

RACT (*Continue on reverse if necessary and identify by block number*)

RIBUTION / AVAILABILITY OF ABSTRACT CLASSIFIED/UNLIMITED ☐ SAME AS RPT. ☐ DTIC USERS	21. ABSTRACT SECURITY CLASSIFICATION
ME OF RESPONSIBLE INDIVIDUAL	22b. TELEPHONE (*Include Area Code*) | 22c. OFFICE SYMBOL

n 1473, JUN 86 *Previous editions are obsolete.* SECURITY CLASSIFICATION OF THIS PAGE

NSTRUCTIONS FOR PREPARATION OF REPORT DOCUMENTATION PAGE

GENERAL INFORMATION

accuracy and completeness of all information provided in the DD Form 1473, especially classification and tion limitation markings, are the responsibility of the authoring or monitoring DoD activity.

ause the data input on this form will be what others will retrieve from DTIC's bibliographic data base or may ine how the document can be accessed by future users, care should be taken to have the form completed by dgeable personnel. For better communication and to facilitate more complete and accurate input from the tors of the form to those processing the data, space has been provided in Block 22 for the name, telephone r, and office symbol of the DoD person responsible for the input cited on the form.

information on the DD Form 1473 should be typed.

y information appearing on or in the report, or applying specifically to the report in hand, should be reported. is any doubt, the block should be left blank.

e of the information on the forms (e.g., title, abstract) will be machine indexed. The terminology used should e the content of the report or identify it as precisely as possible for future identification and retrieval.

Unclassified abstracts and titles describing classified documents may appear separately from the documents in an unclassified context, e.g., in DTIC announcement bulletins and bibliographies. This must be considered in the preparation and marking of unclassified abstracts and titles.

Defense Technical Information Center (DTIC) is ready to offer assistance to anyone who needs and requests it.
Call Data Base Input Division, Autovon 284-7044 or Commercial (202) 274-7044.

SECURITY CLASSIFICATION OF THE FORM

ccordance with DoD 5200.1-R, Information Security Program Regulation, Chapter IV Section 2, paragraph 4-200, cation markings are to be stamped, printed, or written at the top and bottom of the form in capital letters that ger than those used in the text of the document. See also DoD 5220.22-M, Industrial Security Manual for arding Classified Information, Section II, paragraph 11a(2). This form should be unclassified, if possible.

SPECIFIC BLOCKS

Block 1a. Report Security Classification: Designate the highest ity classification of the report. (See DoD 5220.1-R, Chapters I, IV, I, Appendix A.)

Block 1b. Restricted Marking: Enter the restricted marking or ing notice of the report (e.g., CNWDI, RD, NATO).

Block 2a. Security Classification Authority: Enter the monly used markings in accordance with DoD 5200.1-R, Chapter ection 4, paragraph 4-400 and 4-402. Indicate classification ority.

Block 2b. Declassification / Downgrading Schedule: Indicate ific date or event for declassification or the notation, ginating Agency Determination Required" or "OADR." Also t (when applicable) downgrade to ____________ ____________ (e.g., Downgrade to Confidential on 6 July). (See also DoD 5220.22-M, Industrial Security Manual for guarding Classified Information, Appendix II.)

E: Entry must be made in Blocks 2a and 2b except when the original report is unclassified and has never been upgraded.

Block 3. Distribution/Availability Statement of Report: Insert the ement as it appears on the report. If a limited distribution ement is used, the reason must be one of those given by DoD ctive 5200.20, Distribution Statements on Technical Documents, pplemented by the 18 OCT 1983 SECDEF Memo, "Control of assified Technology with Military Application." The Distribution ement should provide for the broadest distribution possible in limits of security and controlling office limitations.

Block 4. Performing Organization Report Number(s): Enter the ue alphanumeric report number(s) assigned by the organization nating or generating the report from its research and whose appears in Block 6. These numbers should be in accordance ANSI STD 239.23-74, "American National Standard Technical rt Number." If the Performing Organization is also the toring Agency, enter the report number in Block 4.

Block 5. Monitoring Organization Report Number(s): Enter the unique alphanumeric report number(s) assigned by the Monitoring Agency. This should be a number assigned by a DoD or other government agency and should be in accordance with ANSI STD 239.23-74. If the Monitoring Agency is the same as the Performing Organization, enter the report number in Block 4 and leave Block 5 blank.

Block 6a. Name of Performing Organization: For in-house reports, enter the name of the performing activity. For reports prepared under contract or grant, enter the contractor or the grantee who generated the report and identify the appropriate corporate division, school, laboratory, etc., of the author.

Block 6b. Office Symbol: Enter the office symbol of the Performing Organization.

Block 6c. Address: Enter the address of the Performing Organization. List city, state, and ZIP code.

Block 7a. Name of Monitoring Organization: This is the agency responsible for administering or monitoring a project, contract, or grant. If the monitor is also the Performing Organization, leave Block 7a. blank. In the case of joint sponsorship, the Monitoring Organization is determined by advance agreement. It can be either an office, a group, or a committee representing more than one activity, service, or agency.

Block 7b. Address: Enter the address of the Monitoring Organization. Include city, state, and ZIP code.

Block 8a. Name of Funding/Sponsoring Organization. Enter the full official name of the organization under whose immediate funding the document was generated, whether the work was done in-house or by contract. If the Monitoring Organization is the same as the Funding Organization, leave 8a blank.

Block 8b. Office Symbol: Enter the office symbol of the Funding/Sponsoring Organization.

Block 8c. Address. Enter the address of the Funding/Sponsoring Organization. Include city, state and ZIP code.

Block 9. Procurement Instrument Identification Number: For a contractor grantee report, enter the complete contract or grant number(s) under which the work was accomplished. Leave this block blank for in-house reports.

Block 10. Source of Funding (Program Element, Project, Task Area, and Work Unit Number(s): These four data elements relate to the DoD budget structure and provide program and/or administrative identification of the source of support for the work being carried on. Enter the program element, project, task area, work unit accession number, or their equivalents which identify the principal source of funding for the work required. These codes may be obtained from the applicable DoD forms such as the DD Form 1498 (Research and Technology Work Unit Summary) or from the fund citation of the funding instrument. If this information is not available to the authoring activity, these blocks should be filled in by the responsible DoD Official designated in Block 22. If the report is funded from multiple sources, identify only the Program Element and the Project, Task Area, and Work Unit Numbers of the principal contributor.

Block 11. Title: Enter the title in Block 11 in initial capital letters exactly as it appears on the report. Titles on all classified reports, whether classified or unclassified, must be immediately followed by the security classification of the title enclosed in parentheses. A report with a classified title should be provided with an unclassified version if it is possible to do so without changing the meaning or obscuring the contents of the report. Use specific, meaningful words that describe the content of the report so that when the title is machine-indexed, the words will contribute useful retrieval terms.

If the report is in a foreign language and the title is given in both English and a foreign language, list the foreign language title first, followed by the English title enclosed in parentheses. If part of the text is in English, list the English title first followed by the foreign language title enclosed in parentheses. If the title is given in more than one foreign language, use a title that reflects the language of the text. If both the text and titles are in a foreign language, the title should be translated, if possible, unless the title is also the name of a foreign periodical. Transliterations of often used foreign alphabets (see Appendix A of MIL-STD-847B) are available from DTIC in document AD-A080 800.

Block 12. Personal Author(s): Give the complete name(s) of the author(s) in this order: last name, first name, and middle name. In addition, list the affiliation of the authors if it differs from that of the performing organization.

List all authors. If the document is a compilation of papers, it may be more useful to list the authors with the titles of their papers as a contents note in the abstract in Block 19. If appropriate, the names of editors and compilers may be entered in this block.

Block 13a. Type of Report: Indicate whether the report is summary, final, annual, progress, interim, etc.

Block 13b. Time Covered: Enter the inclusive dates (*year, month, day*) of the period covered, such as the life of a contract in a final contractor report.

Block 14. Date of Report: Enter the year, month, and day, or the year and the month the report was issued as shown on the cover.

Block 15. Page Count: Enter the total number of pages in the report that contain information, including cover, preface, table of contents, distribution lists, partial pages, etc. A chart in the body of the report is counted even if it is unnumbered.

Block 16. Supplementary Notation: Enter useful information about the report in hand, such as: "Prepared in cooperation with...," "Translation at (or by)...," "Symposium...," If there are report numbers for the report which are not noted elsewhere on the form (such as internal series numbers or participating organization report numbers) enter in this block.

Block 17. COSATI Codes: This block provides the subject coverage of the report for announcement and distribution purposes. The categories are to be taken from the "COSATI Subject Category List" (DoD Modified), Oct 65, AD-624 000. A copy is available on request to any organization generating reports for DoD. At least one entry is required as follows:

Field - to indicate subject coverage of report.

Group - to indicate greater subject specificity of information in the report.

Sub-Group - if specificity greater than that shown by Group is required, use further designation as the numbers after the period (.) in the Group breakdown. Use only the designation provided by AD-624 000.

Example: The subject "Solid Rocket Motors" is Field 21, Group 08, Subgroup 2 (page 32, AD-624 000).

Block 18. Subject Terms: These may be descriptors, keywords, posting terms, identifiers, open-ended terms, subject headings, acronyms, code words, or any words or phrases that identify the principal subjects covered in the report, and that conform to standard terminology and are exact enough to be used as subject index entries. Certain acronyms or "buzz words" may be used if they are recognized by specialists in the field and have a potential for becoming accepted terms. "Laser" and "Reverse Osmosis" were once such terms.

If possible, this set of terms should be selected so that the terms individually and as a group will remain UNCLASSIFIED without losing meaning. However, priority must be given to specifying proper subject terms rather than making the set of terms appear "UNCLASSIFIED." Each term on classified reports must be immediately followed by its security classification, enclosed in parentheses.

For reference on standard terminology the "DTIC Retrieval and Indexing Terminology" DRIT-1979, AD-A068 500, and the DoD "Thesaurus of Engineering and Scientific Terms (TEST) 1968, AD-672 000, may be useful.

Block 19. Abstract: The abstract should be a pithy, brief (preferably not to exceed 300 words), factual summary of the most significant information contained in the report. However, since the abstract may be machine-searched, all specific and meaningful words and phrases which express the subject content of the report should be included, even if the word limit is exceeded.

If possible, the abstract of a classified report should be unclassified and consist of publicly releasable information (Unlimited), but in no instance should the report content description be sacrificed for the security classification.

NOTE: **An unclassified abstract describing a classified document may appear separately from the document in an unclassified context e.g., in DTIC announcement or bibliographic products. This must be considered in the preparation and marking of unclassified abstracts.**

For further information on preparing abstracts, employing scientific symbols, verbalizing, etc., see paragraphs 2.1(n) and 2.3(b) in MIL-STD-847B.

Block 20. Distribution / Availability of Abstract: This block must be completed for all reports. Check the applicable statement: "unclassified / unlimited," "same as report," or, if the report is available to DTIC registered users "DTIC users."

Block 21. Abstract Security Classification: To ensure proper safeguarding of information, this block must be completed for all reports to designate the classification level of the entire abstract. For CLASSIFIED abstracts, each paragraph must be preceded by its security classification code in parentheses.

Block 22a,b,c. Name, Telephone and Office Symbol of Responsible Individual: Give name, telephone number, and office symbol of DoD person responsible for the accuracy of the completion of this form.

★ U.S. Government Printing Office: 1986-

Front Cover

CONTRACT NO.:

TITLE:

PRINCIPAL INVESTIGATOR:

PI ADDRESS:

REPORT DATE ____________________

TYPE OF REPORT ____________________

PREPARED FOR: US ARMY MEDICAL R'& D COMMAND
FT. DETRICK
FREDERICK, MD 21701-5012

DISTRIBUTION STATEMENT:

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

_____Where copyrighted material is quoted, permission has been obtained to use such material.

_____Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

_____Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

_____In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

_____For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.

_____In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

PI Signature Date

APPENDIX L: USAMRDC FORM 9

1. POLICY: The USAMRDC Form 9, Recommendation for Support of Research and Development Project, shall be used to request:

a. Solicitations

b. Initiation of contracts and grants

c. Intragovernmental transfer of funds.

d. All modifications to grants, contracts and fund transfer instruments

2. FORM COMPLETION NOTES:

a. Ordinarily, the Form 9 will be completed by or with the AMLO at each laboratory/institute. Current procedures for using and completing the form are in the USAMRDC Standing Operating Procedure No. 11.

b. The backside of the form cites a number of issues relating to the proposed project which need elaboration if the funding document or change requested is to meet USAMRDC financial and programmatic responsibilities. The backside is often just the first of a number of pages of supporting narrative or documentation which address those topics or issues. Incomplete and/or poorly thought-out material here are greatly responsible for delays in activating the basic request of the Form 9.

3. SOME COMMON ERRORS:

a. Budget figures on the front and back of the form, and in the PI proposal do not agree.

b. Recommended budget does not reflect proposed changes in the SOW submitted by the PI. The budget proposed by the PI comes through even with additions or deletions to the work.

c. General or incomplete SOW which leave everyone unsure of exactly what the PI or contractor is to do.

d. The use of the ambiguous phrase, "- shall include, but not be limited to-" in the SOW. This provides no guidance in either writing or monitoring a contract.

e. Deliverables (compounds, hardware, etc) are expected, but no realistic estimate of what, how much, or when is given.

best copy available

f. Specific reporting requirements are not specified.

g. Conflicting comments in the supporting documentation. e.g. PI is judged to be marginal in one paragraph, then cited as the world's best in another.

h. Unrealistic cuts proposed for the budget. It doesn't necessarily follow, for example, that reducing the effort by half will have the same effect on the budget.

i. The need for human or animal use review and approvals is sometimes not indicated on the front of the Form 9.

j. The Investigator's Address is often entered as the address of the Contracting Organization. The latter is usually a general university address, for example, and does not have the department of chemistry or microbiology, etc.

k. The recommendations, requests and documentation material is not limited to the space on the back of the Form 9.

l. If multiple copies of the Form 9 package are needed, be sure that the copies are complete.

APPENDIX M: INTRAGOVERNMENTAL TRANSFER OF FUNDS

Overview: A very large portion of USAMRDC extramural funding is awarded to other Governmental agencies who conduct research and development projects in support of the USAMRDC mission. Two important points should be noted:

1. The laboratory/institute Commander or Research Area Director (RAD) who wants work performed by another Government Agency may deal directly with the PI and his agency to determine their interest in the project and their capability to perform the associated tasks. The discussions will decide the SOW, budget, conditions of the project, and any other factors which bear on successful completion of the work. This is in obvious contrast to the procedures in the negotiated acquisition process required when dealing with organizations outside the Government.

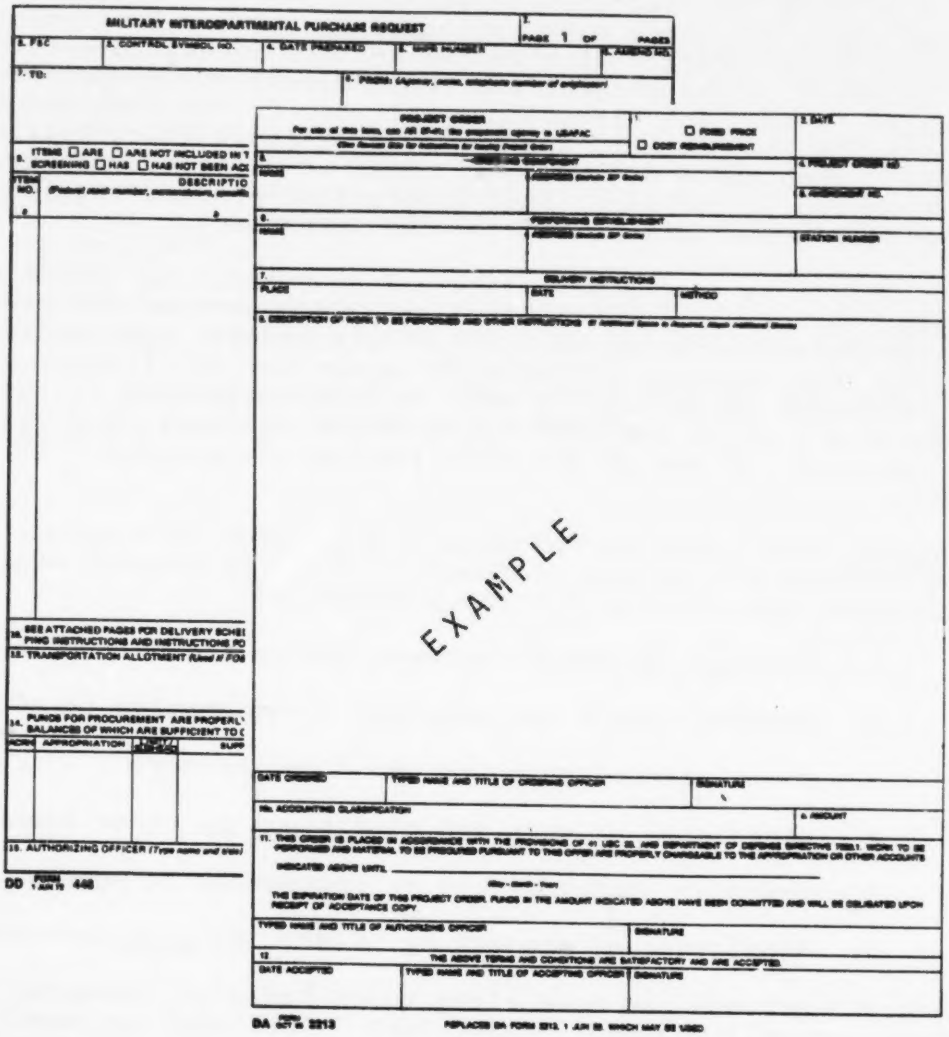
2. It is in the best interest of USAMRDC to impose the same requirements on projects done at other Government agencies, as on projects done under contract. Accordingly, SOW, budgets, reporting requirements, HURRAO/AURO issues and compliance, and any other necessary conditions of work will be documented in the USAMRDC Form 9 which requests the transfer of funds, and will be fully monitored by the PO and "COR" during the execution of the project.

Procedure: The procedure for obtaining project work using intragovernmental transfer of funds is given in USAMRDC Acquisition Instructions. In brief, the process is:

1. Informal agreement between Agency and USAMRDC PO.
2. USAMRDC Form 9 and complete documentation to ACQ.
3. Formal presentation to the other Agency.
4. Acceptance of work and conditions by other Agency.
5. Transfer of funds (all or increment) to Agency.
6. Monitoring of project by USAMRDC program personnel.

The overall process can move along quite rapidly. However, a complete and well planned USAMRDC Form 9 "package" is essential to speed and accuracy in transferring funds and, thus, in initiating the desired research effort. The Form 9 for intragovernmental transfer of funds shall be completed in virtually the same detail as requesting a contract or grant. Remember, the Forms which are shown on the next page are only the cover of a funding document that can run to 8-10 pages.

There are special procedures to be followed for the processing of Health Services Command (HSC) Clinical Investigation Protocols and also Clinical Investigation Combat Casualty Care Program (CIC^3) Protocols. These procedures are detailed in USAMRDC Standing Operating Procedures on the Extramural Program No. 12.



MILITARY INTERDEPARTMENTAL PURCHASE REQUEST

PAGE 1 OF PAGES

7. TO:

ITEMS ☐ ARE ☐ ARE NOT INCLUDED IN T

SCREENING ☐ HAS ☐ HAS NOT BEEN AC

DESCRIPTIO

DD FORM 448

PROJECT ORDER

☐ FIXED PRICE

☐ COST REIMBURSEMENT

2. DATE

DELIVERY INSTRUCTIONS

PLACE

DATE

METHOD

DATE ORDERED

TYPED NAME AND TITLE OF ORDERING OFFICER

SIGNATURE

TYPED NAME AND TITLE OF AUTHORIZING OFFICER

SIGNATURE

DATE ACCEPTED

TYPED NAME AND TITLE OF ACCEPTING OFFICER

SIGNATURE

DA FORM 2213

Forms : One of two forms is used as the basic USAMRDC presentation and Agency acceptance document; DA Form 2213 "Project Order", or DD Form 448 "Military Interdepartmental Purchase Request". USAMRDC prefers using the DA Form 2213 "Project Order" for transfers to all Agencies, DOD and civilian. The one that is finally used depends largely on the needs or desires of the other Agency. Samples of the two forms are shown above.

APPENDIX N: WRITING STATEMENTS OF WORK

A. Introduction

1. The Statement of Work (SOW) is the most important section of the contract. A good SOW will define the Government's needs by specifying:

a. Who;

b. What;

c. When;

d. Where; and

e. How (not always).

2. A complete and concise SOW will cause proposers to prepare intelligent and competitive proposals. The well written SOW will be a document which will be understandable to all who must work with the contract. A good SOW will improve effectiveness and efficiency.

3. Each SOW is unique to get what the Government needs.

4. The term "Scope of Work" should not be confused with the "Statement of Work." The Scope of Work is a summary of the entire SOW. When writing this section, the SOW author should assure that the scope and objective are consistent with the level of funding available.

5. The title of the research and Scope of Work should clearly summarize the contract. Auditors and inspectors are closely monitoring contracts to identify and control consulting services, defined as studies to analyze support or improve activities such as policy development, decision making, and management. Descriptive titles and Scope of Work should not infer that basic Government functions of planning; policy development, interpretation and enforcement; program and budget decision-making; and, financial accountability are being performed by contract.

B. Hints for Writing Statements of Work

Written documents must accurately inform a reader. Good writing will accurately and efficiently convey information. A good guide for writing is Strunk and White's The Elements of Style.

The following are some specific points to consider when writing a SOW.

1. Use simple, direct and clear language. Clarity is achieved by using short words. Words with multiple meanings should be avoided. Vague words should be defined.

2. Use active verbs. Passive verbs can be vague. For example, specify who will do something and when. This is important in research and development because many contractor's activities depend on the Government first doing something.

3. Use adjectives sparingly. Adjectives soften nouns and make their meaning vague. For example, adjectives such as "workmanlike," "successful," "substantial," and "reasonable" obscure the contractor's obligation.

4. Use language consistently. Do not change a word or phrase unless a change in meaning is intended. The repetition of long, awkward phrases can be avoided by inventing a name and using it consistently; thus, "the XYZ Company, Inc. (herein called the Contractor)."

5. Use "and/or" sparingly. The use of and/or can be confusing. This is one place where the rule of using as few words as possible can be ignored. For example, if the SOW says, "The contractor shall supply A, B, and/or C," there is confusion about what the contractor is required to supply. If the contractor has the choice of supplying any or all of the three items, the SOW should state: "The Contractor shall supply either A, B, or C, all of them, or any combination of them".

6. Time. When something must be done, it must be stated. For example: "On January 2, the Contractor shall submit a report . . ." Sometimes a report will depend on contingencies. One of the most annoying contingencies is the uncertainty about when the contractor started work. To solve this problem the SOW should state: "delivery within 90 days . . ." and an event should be specified. Avoid "90 days from the award of the contract" because this is ambiguous. "Awarded" may mean the time the Government decided who the contractor was to be, the date of approval by the Contracting Officer, or the date the contract was signed. To avoid this kind of ambiguity, say "90 days from the effective date of the contract". The "effective date" is defined by the phrase: "The contract made as of the 1st of January . ." and it gives a firm base from which to start.

7. Incorporation by reference. Often there is a need to incorporate some other document into the SOW. The incorporated document should be identified by date, title, and reference number. The incorporated document should be attached, or its location stated. If "standard tables" are incorporated, the drafter should be clear about which tables these are and know exactly what they say. They may include material that might be objectionable to the Government.

8. Agreements to agree. Caution should be exercised in "agreeing to agree" in the future on some significant point, because this may cause difficulties later. If "the model is to be painted a color to be mutually agreed upon" and the drafter really does not care what color it is -- then no harm is done. But if the color is significant, the matter should not be left open.

9. Theoretical discussion. Sometimes theoretical discussion is included in a SOW, with confusing results. If it is necessary to include scientific background or theoretical reasons for doing the work, the drafter should try to do this in a separate part of the SOW so that there will be a clear line of demarcation between the "why" and the "what". The SOW should consist of a description of work.

C. SOW Wording Hints

	Instead of:	Use:
WASTEFUL	afford an opportunity	allow
	gained from the following	from
	in a manner similar to	like
	in a situation in which	when
	make provisions for	provide for
	with due regard for	for
	prepare a draft	draft
PRETENTIOUS	utilization	use
	elucidate	explain
	ascertain	determine

* * *

AMBIGUOUS	similar	Use measurable standards
	average	Use measurable standards
	about	
	reasonable	
	good	
	rapid	
	skillful	

where practical

suitable

DO NOT USE

"assist" - infers personal services situation.

"as required" - has no expressed limitations.

"as necessary" - leaves requirements to the Contractor.

"as directed" - infers personal services situation.

SHALL and WILL

The term "shall" makes provisions binding and mandatory for the Contractor.

The term "will" expresses commitment by the Government.

D. SOW Wording Problems. The following pages are a short exercise on composition errors which make many SOW confusing to the Contractor. The limited number of samples is aimed more at creating an appreciation of the problem than at providing the final solution. There are too many variations in tasks, conditions, and writers to come up with a single, manageable template.

The exercise consists of three parts:

a. Sample is an SOW statement as it appeared in a USAMRDC draft or contract SOW. Some changes were made to mask the origin and to highlight problems.

b. The Problems portion cites errors or problems which need consideration in making the SOW more effective.

c. Better is offered as an improvement of Sample.

The exercise does not address one very important point - A lack of appropriate detail is the single-most prevalent shortcoming afflicting draft SOW submitted in support of a request for contracting. The result is a time-consuming, retrospective search for the information needed both to protect the Government's interest and to adequately describe the Contractor's task.

Sample 1:

"Prepare approximately a 200-word abstract outlining the proposed work."

Problems:

This is awkward sentence structure that does not say what is intended. As presented, the word "approximately" relates to "prepare", not to "abstract". Moreover, the use of two action words (prepare and outlining) seems unnecessary.

Better:

Outline the proposed work in an abstract of approximately 200 words.

Sample 2:

"The U.S. Army Medical Research and Development Command is the Department of Defense's lead agency for . . . ."

Problems:

Assignment of the 'possessive' to inanimate entities is inappropriate.

Better:

The U.S. Army Medical Research and Development Command is the lead Department of Defense agency for . . . .

Sample 3:

"Congress appropriated $37M for the U.S. Army to carry out research on AIDS."

Problems:

There are several concerns in this sample. First, the size of the program that supports an acquisition does not provide insight into the scope of the specific effort. Second, "to carry out research on" is wordy. Third, the acronym "AIDS" is not defined. If possible, it would be helpful to state the types of "research" which comprise the Army program.

Better:

Congress has tasked the U.S. Army to study etiological and causative aspects of Acquired Immune Deficiency Syndrome (AIDS).

Sample 4:

"The contractor shall have access to scientific and technical personnel who understand and can assess, critique, summarize, and make recommendations on research and programmatic issues . . ."

Problems:

The "understand" phrase is redundant.

Better:

The contractor shall have access to scientific and technical personnel who can assess, critique, summarize, and make recommendations on research and programmatic issues . . ."

Sample 5:

"Provide support for approximately four (4) after-action meetings per year held by MCDPRC to review both MCDPRC recommendations and programmatic issues."

Problems:

* What does "after-action" mean?

* The acronyms are confusing in their similarities.

* The phrase "both MCDPRC recommendations and programmatic issues" has several interpretations, among which may be the need to review "two" MCDPRC recommendations.

Better:

Provide support for approximately four (4) MCDRP management staff meetings per year to review program issues and Peer Review Committee recommendations.

Sample 6:

"Four meetings will be held in nongovernment facilities. The contractor is to select the meeting sites, and negotiate for suitable meeting rooms and conference support. For all meetings, the contractor is to make arrangements for travel and accommodations for nongovernment participants."

Problems:

The statement leaves virtually everything (time, location, facilities, etc.) to the contractor.

Better:

The Contractor shall arrange a meeting at each of four nongovernment, U.S. facilities over the course of the contract. All plans shall be approved by the COR and shall meet the provisions of the DoD Joint Travel Regulations. The contractor shall mail pertinent documents and instructions to all participants, who then meet their own travel and personal needs.

Sample 7:

"One additional nurse will be required to keep records on a special study as well as take histories and administering the questionnaire. The additional duties would be drawing blood, filling out standard interview forms, maintain the data forms, and the laboratory test results. A protocol has been approved for the special study. This additional nurse also reports potentially adverse reactions to the physician who is the PI. The patient is the physician's responsibility."

Problems:

Poor organization and complex sentences lacking parallel construction confuse the entire 'requirement'. One must search to find the nurse duties. There is no indication of work, or patient load, that can be used for funding the position. The third sentence is an out-of-place afterthought. The only clear point is that the nurse is not responsible for the patient.

Better:

One additional nurse will be needed to work with 5-10 patients per week in a special study to be conducted in parallel with the basic survey. The additional nurse shall:

a. Draw patient blood samples for laboratory tests.

b. Interview each patient while completing a standard interview form.

c. Maintain patient files of data forms and laboratory test results.

d. Advise the patient's physician of potentially adverse reactions.

e. As time permits, take histories and administer question naires in the basic survey.

Sample 8:

"In administering the Government-provided questionnaire the Contractor shall:

a. Provide the questionnaire to the patient for completion but remain available to assist the patient as needed in completing the questionnaire.

b. In the event the patient, with Contractor assistance, is not able to complete the questionnaire the Contractor shall consult with the patient's attending physician.

c. Depending on the results of the consultation with the attending physician the Contractor shall review existing specific patient medical records and laboratory reports as necessary.

Problems:

The statement is missing approximately six commas and contains too many "the Contractor shall". It is also too long and cumbersome for expressing only two points.

Better:

The Contractor shall:

a. Issue the Government-provided questionnaire to each patient and, as necessary, assist with its completion.

b. Consult with the attending physician for direction in using medical records and laboratory reports as substitute sources when the patient is unable to complete the questionnaire.

Sample 9:

"Review all contract reports, including those for publication and maintain a cumulative summary of key accomplishments and an assessment of their impact on programs, as well as a historical track of issues and their resolutions."

Problems:

This single 'sentence' requirement is poorly constructed and masks what needs to be done. Phrases and clauses seem to be afterthoughts. It is difficult to see the writer's full intent; the "Better" recommendation may miss the point!

Better:

Review all contract reports, manuscripts and publications for key accomplishments.

a. Summarize the key accomplishments and assess the impact of each on the programs. Maintain a list of accomplishments for each contract effort.

b. Maintain an historical track of program issues and their address or resolution by the key accomplishments.

Sample 10:

"Within two (2) days following contract award, the Contractor shall submit for Government approval, a proposed shipping form, an example of which can be found at Technical Exhibit No. 1. The

Government will render acceptance or rejection of the proposed shipping form within three (3) days thereafter."

Problems:

This is a good example of awkward structuring, unnecessary phrases, and stilted wording. The points are there, but they are hazy. Keep the writing simple and clear.

Better:

Within two (2) working days following contract award, the Contractor shall propose a shipping form patterned after the example found at Technical Exhibit No. 1. The Government has three (3) working days to accept or reject the proposed form.

Sample 11:

Upon completion of a questionnaire, the Contractor shall:

a. Telefax a copy of the questionnaire within one working day of its completion, to USAMRDC at the address designated in Section F, Subparagraph 1.

b. In the event the contractor's telefax machine is malfunctioning the Contractor shall send within one working day of completion, via registered mail, a copy of the questionnaire to the address designated in Section F, Subparagraph 2.

Problems:

The statement contains several examples of embellished wording; for instance, using "completion of" rather than "completing", "via" instead of "by", and "designated" rather than "given" or "shown". The phrases "the contractor shall" and "within one working day of completion" are unnecessary repetitions.

Telefax is a specific trade name. It is incorrect to use it in place of the generic "facsimile transceiver", unless the Telefax brand is actually required in the work.

The reference to problems with the Contractor's facsimile does not address the possibility of problems at USAMRDC. Both events would seem to have the same undesired result and require the same remedy.

Better:

Upon completing a questionnaire, the Contractor shall:

a. Within one working day, transmit the questionnaire by facsimile transceiver to USAMRDC at the address given in Section F, Subparagraph 1.

b. In the event of facsimile transceiver problems, send hard copy of the questionnaire by registered mail to USAMRDC at the address given in Section F, Subparagraph 2.

Sample 12:

"The specific work will encompass:

1. Comparison of the effectiveness and toxic effects of the single drugs, A, B, C, and D. The most potent drugs with favorable therapeutic indices will then be chosen to screen for additive and/or synergistic efficacy.

2. Drugs supplied by USAMRDC.

3. Additional studies in the proposal are incorporated into this workscope by reference, and consent of COR."'

Problems:

The words "specific work" imply that there is 'nonspecific work' The requirement is presented in a passive form which fails to state precisely what work is to be done and who is to do it. The indefinite, "will encompass", may permit unneeded work. Item 1. calls for a "comparison". The first and much more costly, time-consuming and difficult step which should be highlighted is the laboratory work which precedes the comparison. The phrase "additive and/or synergistic efficacy" permits the Contractor to look for one or both effects, as he desires. As a practical matter, the statement overlooks the possibility that the synergism of the two, least potent single drugs may give the best overall efficacy. Item 2, how many USAMRDC drugs are involved? Item 3 will not be acceptable to the Contracting Officer. If the other studies are important, cite or describe them explicitly in the SOW. If they depend on preliminary findings, explain how they would become a part of the contract effort. Note, of course, that they only become part of the effort with COR concurrence and Contracting Officer approval. A time frame is needed to divide the Contractor efforts between the single and combined drug studies.

Better:

The Contractor shall:

1. Determine the individual effectiveness and toxicity of:

    a. Drugs A, B, C, and D.
    b. Drugs E, F, and G, as supplied by USAMRDC.

2. Screen pairs of the most potent of drugs A-G having favorable therapeutic indices to determine their combined efficacy and toxicity.

3. Conduct additional studies outlined in the proposal and addendum as project conditions warrant. However, studies beyond those in Items 1 and 2 will not be undertaken without COR concurrence and Contracting Officer approval.

It is expected that the work in Item 1 will be completed within eighteen (18) months after the effective date of the contract. The balance of the contract term will be used to address Item 2 and, as approved, Item 3.

GLOSSARY OF ACQUISITION TERMS

Acquisition-- Using appropriated funds to acquire supplies or services by contract, by and for the Federal Government through purchase or lease. Acquisition begins at the point when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and those technical and manage ment functions directly related to the process of fulfilling agency needs by contract.

Acquisition Instructions (AI)-- The collected instructions, policies and procedures governing the acquisition of the USAMRDC extramural research and development efforts. The AI are promulgated by the PARC.

Acquisition Management Liaison Office (AMLO)-- An acquisition staff function found in all USAMRDC laboratories and institutes having significant extramural research interests or commitments. The precise role of each AMLO in the acquisitions process depends on the desires of the local commander. Typically, AMLO serve as their commander's liaison with the acquisition process, coordinate and facilitate the acquisitions responsibilities of the laboratory/institute, and provide assistance that will increase the effectiveness and ease the burden of the COR tasks in their laboratory/institute. Each AMLO will normally describe local policy in written directives and in briefings.

Acquisition Plan-- A plan required by the FAR for very large acquisitions. It covers the entire acquisition process from need, through consideration of planning issues, to the selection and award procedure.

Acquisition Requirements Package (ARP)-- USAMRDC Form 9 and supporting documentation submitted by program personnel to USAMRAA requesting a solicitation and award of contract(s).

Advance Acquisition Plan-- A administrative document used for establishing priorities in the USAMRDC contracting process.

Apparent Authority-- This is a private sector term for the situation that is created when a principal acts in such a manner that another appears to be his or her agent. Apparent authority creates an agency relationship where none existed previously, or establishes authority other than actual authority. In commercial contracts, the principal is liable for the acts of its agent performed within the limits of the agent's apparent authority. However, this does not apply to the Government or Government contracts.

Associate Director of Small and Disadvantaged Business Utilization (ADSADBU)-- The specialist who administers the USAMRDC special socioeconomic acquisition programs.

Broad Agency Announcement (BAA)-- A formal, published and widely distributed announcement which outlines general USAMRDC research needs and invites proposals which address them. The BAA serves as an RFP which supplants the more time-consuming, normal RFP process. It has its greatest utility in the tech base research program.

Business Clearance Memorandum--This is a complete record of all actions leading to award of a contract. It records the history of the acquisition and explains and supports the rationale, judgments, and authorities upon which all decisions and actions are predicated.

Business Evaluation-- Measuring a business proposal against the business requirements of the acquisition and rating the proposal accordingly.

Commerce Business Daily-- A daily list of U.S.Government acquisition invitations, subcontracting leads, contracts awarded, sales of surplus property, and foreign business opportunities.

Competition Advocate-- The person within each acquisition activity that is responsible for challenging barriers to, and promoting, full and open competition.

Constructive Change-- A contract change caused by Government mishandling of contract provisions and/or oversight, usually to the detriment of the Government.

Contract Administration-- The management of all facets of contracts to assure that the contractor's total performance is in accordance with its contractual commitments and that the obligations of the Government are fulfilled.

Contracting Officer-- The individual appointed as the Government's authorized agent in dealing with the contractor. This individual has authority to negotiate and award contracts on behalf of the Government and to make changes and amendments to the contract.

Contracting Officer's Representative (COR)-- The technical, or program person who is appointed by the Contracting Officer to monitor the technical, or scientific aspects of a contract effort on behalf of the Government. The ideal situation would have the PO initially involved with the project and planning as the COR. In many instances, however, COR have had small, if any, roles in planning for and placing the contracts which they monitor. Most perform the COR function as an additional duty, and have minimal knowledge of and experience with the acquisition process. While the material in this Guide applies to all USAMRDC COR, the level is aimed at that majority. Details of the COR function are centered in Sections V - VII.

Contract Negotiator-- The USAMRAA contract specialist assigned to negotiate the contract up to, but not including, the point of signature. The contracting officer who signs the contract may act as the contract negotiator.

Contractor-- An organization which enters into a written agreement (contract) with USAMRDC (Government) to provide stated services (research, etc) for certain costs. Note that the contractor is an organization (corporation, university, etc), not an individual. Note, also, that the term, Contractor, extends to other Government agencies when considering the material and provisions in Section VI: Post-Award Administration.

Federal Acquisition Regulation (FAR)-- The regulation governing Federal agencies to in the acquisition of supplies and services with appropriated funds.

Head of Contracting Activity (HCA)-- The Commanding General, USAMRDC, who is ultimately responsible for the effective and legal execution of the USAMRDC program.

Historically Black Colleges-- Colleges or universities which were originated for the education of blacks. The ADSADBU has the current listing of these schools and any information regarding special or set-aside treatment in contract funding.

Intragovernmental Transfer of Funds-- The procedure by which USAMRDC supports other Government agencies in their conduct of studies on behalf of USAMRDC mission needs.

Incremental Funding-- An incrementally funded contract is a contract in which the total work effort is to be performed over multiple time periods and funds are allotted to cover discernible phases or increments of performance.

Justification and Approval-- The procedure and format needed to justify and, subsequently, obtain approval for an acquisition through other than full and open competition.

Level of Effort-- This type of contract obligates the contractor to devote a specified level of effort for a stated period of time. Usually the minimum and maximum number and type of person-hours or person-months that the Government is purchasing are specified in the contract.

Negotiation-- This term refers to the making of purchases and contracts without formal advertising. Under negotiated contracts, the lowest offeror does not necessarily receive the award. Award is made on the basis of the proposal that offers the greatest advantage to the Government, price and other factors considered.

Offeror-- An individual or firm responding to a solicitation.

Phasing-- The dividing of the contractual effort into discrete components or stages of accomplishment, each of which must be completed and approved before the contractor may proceed to the next phase.

Pre-award Survey-- Investigation of a firm's management and resources in order to forecast the potential to perform under a proposed contract or to reveal whether the offeror's financial and accounting systems are reliable for cost accumulation and billing.

Prenegotiation Conference-- Meeting of the Government negotiation team in which negotiation goals are developed prior to negotiation with the contractor.

Principal Assistant Responsible for Contracting (PARC)-- The senior staff official responsible for oversight and administration of the contracting function within USAMRDC. The PARC promulgates policy and direction both for contracting and for acquisition from intragovernmental sources.

Principal Investigator (PI)-- The individual(s) with the primary role in conducting or coordinating the contract effort for the contractor. This is the person with whom the COR is most likely to have direct contact during the performance of the contract. It is important that the PI realizes that he is not the contractor and cannot obligate his organization in any contract matter. University PI, in particular, tend to overlook this fact.

Program Officer (PO)-- A program representative responsible for coordinating with acquisition officials on projects for which contract support is contemplated. This representative may be responsible for technical monitoring and evaluation of the contractor's performance after award.

Proposal Evaluation Criteria-- Criteria against which proposals are evaluated. The RFP must explain these factors and their order of importance.

Request for Proposal (RFP)-- The Government's invitation to prospective offerors to submit a proposal based on the terms and conditions set forth in the RFP.

Section 8(a)-- This section of the Small Business Act (15 USC. 631 et. seq.) requires that a portion of each agency's acquisitions be set-aside for small disadvantaged business concerns, defined as a small business concern that (a) is at least 51 percent owned by one or more individuals who are both socially and economically disadvantaged or a publicly owned business having at least 51 percent of its stock owned by one or more socially disadvantaged individuals and (b) has its management and daily business controlled by one or more such individuals.

Set-Aside-- The restricting of certain acquisitions to response by a specific group of sources.

Source Selection Evaluation Board (SSEB)-- A board, or panel convened by the contracting officer to evaluate the technical and certain business aspects of proposals submitted in response to a solicitation. The report of the board serves as a basis for subsequent negotiations by the contracting officer.

Source Selection Plan-- The plan according to which a solicitation will be conducted. It includes the manner of advertising, proposal evaluation, negotiation and contract award.

Sources for Solicitation-- Prospective offerors to whom the request for proposal will be sent, even though not requested.

Statement of Work (Scope of Work)-- The document that states the technical objectives and requirements of the contract.

Supplemental Agreement-- A modification of an existing contract that is accomplished by the mutual action of the parties.

Synopsis-- A short description of a Government acquisition published in the Commerce Business Daily for one of the following purposes: (1) alerting interested parties to an upcoming acquisition; (2) finding sources to provide services or items to the Government; and (3) informing interested parties of the result of an acquisition.

Technical Evaluation-- Measuring a technical proposal against the technical requirements of the acquisition data and rating the proposal accordingly.

Uniform Contract Format-- The format, prescribed by the FAR, according to which all solicitations and contracts must be drafted.

Unsolicited Proposal-- A research and development proposal that is made to the Government by a prospective contractor without prior formal or informal solicitation from a procuring activity.

INDEX

A-76 Review 31
Acquisition 7, 196
  Integrity of process 111
  Methods 10
  Overview 1
  Personnel roles 3
  Regulations 2
  Roles 1
  Socioeconomic Programs 12
  vs procurement 3
Acquisition cycle 34
Acquisition Data Availability 114
Acquisition Guide 4
  audience 5
  purpose 4
Acquisition Instructions 3
Acquisition issues 147
Acquisition Management Liaison Office (AMLO) 2, 139, 196
Acquisition methods 10
acquisition overview 1
Acquisition path 12
acquisition paths 32
  Broad Agency Announcement 14, 33, 137, 197
  Grants 3
  Intragovernmental Transfer of Funds 7, 33, 182, 198
Acquisition Plan 33
Acquisition Planning 32
  Advance 23
  Concept development 24
  responsibilities 24
Acquisition planning document 29
Acquisition requirements 17
Acquisition Requirements Package 32, 51, 145
action after subcontract award 85
Administration of subcontracts 84
Advance Acquisition Plan 196
Advance Acquisition Planning 23
AMLO 2, 3, 98, 102, 139, 167, 180, 196
Animal use 27, 29, 30, 131, 181
  form 9 181
  performance review 132
  proposal instructions 131
  proposal review 141
Apparent Authority 196
BAA 14, 15, 33, 137, 140, 197
  Policy 137
  Procedures 139
  Responsibilities 138

Best and final offers 14, 65, 66
Blanket Purchase Agreement 17
Blanket purchase agreements 16
Broad Agency Announcement 14, 33, 137, 197
Business Clearance Memorandum 65
CGMP 30
Change Orders 93
CO 1, 4, 7, 9, 12, 14, 16, 22, 24, 31, 37, 47, 49, 53, 56-58, 64, 66, 68, 69, 71, 73, 76, 90, 100, 102, 104, 145
Commerce Business Daily 13, 27, 66, 139, 197, 200
Competition in contracting 10, 14, 137
Conflict of interest 28, 59, 109, 110, 161
Consideration for contract modification 92
Constructive changes 93
    avoidance 95
    causes 94
Contract 31, 132, 138
    format 54
    items 79
    nature of 8
    protests 67
    review 78
    types 153
Contract Administration 75, 197
    resolving disputes 103
Contract award 34
Contract closeout 104, 105
Contract Data Requirements List 37, 145
Contract deliverables 39
contract end
    closeout 105
    files 107
    inspection and acceptance 104
    review and analysis 104
Contract files 107
Contract modifications 91
    change orders 93
    consideration 92
    constructive changes 93
    versus new acquisition 92
Contract monitoring 86
    need 87
    progress reports 87
    site visits 90
contract performance problems 98
contract review and analysis 104
Contract security classification specification 149
Contract type 28
Contracting by negotiation 13
    authority 9
    basics 7

- Contracting for Development 52, 147
    - acquisition issues 147
    - contract types 153
    - definitions 147
    - instructions for CO 151
    - sole source 149
- Contracting Officer 1, 197
- Contracting Officer's Representative (COR) 2, 69, 132, 197
- Contractor 2, 198
- contracts 18
    - cost-reimbursement 19
    - development types 147
    - fixed-price 18
    - follow-on 115
    - fraud 111
    - types 18
- Contracts Disputes Act 103
- COR 2, 69
    - animal use review 132
    - appointment 69
    - cautions 71
    - communications 72
    - contract files 71
    - contract review 78
    - limitations 76
    - responsibilities 69
- COR contract files 71
- Cost and Schedule Performance Data 82
- Cost Overruns 98
- Cost-sharing contracts 21
- Debriefing Unsuccessful Offerors 67
- exclusion of sources 11
- files
    - COR 71
    - end of contract 104
- final reports 168
- fixed-price contract 19
- Full and open competition
    - format 113
    - justifications for other than 27
    - other than 11
    - process 10
- Funding 21
    - full 21
    - incremental 21
    - options 22
- GLP 30
- Government contract administration 75
- Grants 1, 3, 15, 16, 21, 29, 33, 120, 122, 180
- Gratuities 109
- Head of Contracting Activity 198
- Historically Black Colleges 198

Human use 29, 117
    anatomical substances 118
    policy 117
    procedures 121
    provisions 121
    requirements 122, 126
    review/contracting procedures 119
Imprest funds 17
incorporation by reference 185
Independent Government Cost Estimates 44
Inspection and acceptance 104
Intragovernmental Transfer of Funds 7, 119, 180, 182
    Forms 183
    Overview 182
    Procedure 182
Justification and Approval 12
    format 113
Key personnel
    clauses 37, 83
Labor Surplus Area Concerns 13
Level of effort acquisition 45
Manuscripts for Publication 170
Materiel Acquisition Process 24, 45, 135
Medical Materiel Acquisition Management Handbook 45, 52
Method of acquisition 12
Midterm report 167
Misconduct in Science 73
modification versus new acquisition 92
negotiation
    best and final offers 65
    business clearance memorandum 65
    written and oral discussion 64
Negotiations 64
New acquisition 92
PARC 1, 3, 24, 138, 199
Performance Review 132
PI 2
Planning issues 25
    acquisition background 23
    background 25
    objectives 26
    plan of action 27
    special approvals and clearances 29
PO 1, 199
Prenegotiation Conference 199
Principal investigator 2
Prior authorization for expenditures 81
Procedures 15
Procurement Action Lead Time (PALT) 51
Program Officer 1, 59, 199

Progress reports 87, 165
  COR responsibility 89
  final 168
  foreword 170
  format 169
  front cover 170
  midterm 167
  preliminary data 89
  quarterly reports 165
  requirements 88
  Section F 165
Prohibition of Use of Human Subjects 123
Proposal instructions 54, 131
Proposal review 119
Public Information releases 171
Publicizing contract award 66
Purchase Orders 17
Purpose of the contract 25
Request for Proposal 13, 53
  receipt of proposals 56
  uniform contract format 54
RFP proposal evaluation 46
  cost as a criterion 49
  evaluation worksheet 50
  planning 46
  purpose of criteria 46
  sample evaluation criteria format 49
  selecting criteria 47
  weighting criteria 48
RFP proposal review 58
  business/cost proposals 61
  competitive range 62
  evaluation worksheet 50, 133
  reading and scoring proposals 59
  role of Program Officer 59
  Source Selection Evaluation Board (SSEB) 58
Section 8(a) 199
Selection and Award 66
site visits 90
  checklist 90, 163
  Purpose 90
  trip reports 90
small business concerns 13
small disadvantaged business concerns 13
small purchases 16
Socioeconomic Acquisition Programs 12, 28
sole source justification 149

solicitations 53
    amending 56
    communication with offerors 57
    milestones 145
    outline 145
    pre-proposal conferences 55
    receipt and management of proposals 56
    request for proposal (RFP) 53
    schedule 51
    Source Selection Evaluation Board Report 61
Source Selection Evaluation Board (SSEB) 58
    evaluation report 61
    review of proposals 58
Source Selection Plan 33, 201
SOW
    common elements 35
    hints for writing 184
    incorporation by reference 185
    key personnel clauses 37
    outlining 43
    performance vs design specifications 41
    phasing 42
    revising 43
    steps in writing 38
    term vs completion 41
    wording problems 187
Special contract provisions 81
Standards of Conduct 161
Streamlines Medical Materiel Acquisition Program 135
Subcontracts 83
    action prior to award 84
Synopsis 200
terminations
    for Convenience 101
    for Default 102
    of USAMRDC support 102
Unsolicited proposals 15
USAMRDC Form 9 33, 98, 180
    common errors 180
    form completion notes 180
    policy 180
Use of Official Information 110
Withholding payment 100